EXHIBIT G

From: DePasquale, Annmarie (ATSDR/DCHI/CB)
Sent: 14 Sep 2018 18:17:36 +0000
To: Colledge, Michelle (ATSDR/DCHI/CB)
Subject: FW: Consumer Summary: Ethylene Oxide, Sterigenics International (URGENT)
Attachments: Consumer Summary Evaluation of Potential Health Impacts from Ethylene Oxide Emissions v.9.14.18.docx, Sterigenics_International_Inc-508.pdf

Ok, Give me a call on Monday so we can discuss this and the congressional letter.

From: Colledge, Michelle (EPA) (CDC epa.gov)
Sent: Friday, September 14, 2018 12:52 PM
To: DePasquale, Annmarie (ATSDR/DCHI/CB) <and6@cdc.gov>
Cc: Johnson, Mark (EPA) (CDC epa.gov) <JOHNSON.MARK@EPA.GOV>
Subject: Fw: Consumer Summary: Ethylene Oxide, Sterigenics International (URGENT)

ACK! I hit send too quick. Annmarie-please see below/attached.

Michelle A. Colledge MPH, PhD
CAPT, U.S. Public Health Service
Agency for Toxic Substances and Disease Registry/NCEH/CDC, Region 5
77 W. Jackson Blvd., Room 413
Mailstop ATSD-4J
Chicago, Illinois 60604
Tel: 312-886-1462
Fax: 312-886-6066

From: Colledge, Michelle
Sent: Friday, September 14, 2018 11:50 AM
To: (b)(6) Johnson, Mark; Allen-Lewis, Sylvia (ATSDR/DCHI/CB); lob3@cdc.gov
Cc: Hanley, Jack (ATSDR/DCHI/CB)
Subject: Consumer Summary: Ethylene Oxide, Sterigenics International (URGENT)

All:

As some of you know, EtO has become a national issue and we in R5 had the first request from EPA to evaluate EtO emissions. The public outreach was poorly executed for this site, and an ATSDR LHC written to EPA was released without the context of an EPA website to explain the basis/regulatory part of the enforcement work with the company (the EPA facility website was posted, then removed an hour later, and eventually replaced with a very bare site and our document). We had 500 very concerned and angry people at a public meeting where Q&As lasted 4.5 hours.

The completely understandable climate in this community is fear. Our office is fielding calls daily. We desperately need a forward facing document ASAP. Please help us get this one

reviewed and expedited through clearance. I have attached the draft fact sheet and the original LHC.

Thanks in advance for your help and guidance!
Michelle

Michelle A. Colledge MPH, PhD
CAPT, U.S. Public Health Service
Agency for Toxic Substances and Disease Registry/NCEH/CDC, Region 5
77 W. Jackson Blvd., Room 413
Mailstop ATSD-4J
Chicago, Illinois 60604
Tel: 312-886-1462
Fax: 312-886-6066


please consider the environment before printing this email

EXHIBIT H

From: Hanley, Jack (ATSDR/DCHI/CB)
Sent: 10 Oct 2018 14:10:19 +0000
To: Johnson, Mark;And6@cdc.gov
Subject: FW: air sampling user guide - Response to Rep. Foster's office
Importance: High

FYI

From: Williams, Holly G. (CDC/OPHPR/OD)
Sent: Thursday, October 4, 2018 7:54 AM
To: Moore, Susan (ATSDR/DCHI/SSB) <sym8@cdc.gov>; Hanley, Jack (ATSDR/DCHI/CB) <jah8@cdc.gov>; Johnson, Mark (EPA) (CDC epa.gov) <JOHNSON.MARK@EPA.GOV>; Colledge, Michelle (EPA) (CDC epa.gov) <COLLEDGE.MICHELLE@EPA.GOV>
Subject: FW: air sampling user guide - Response to Rep. Foster's office
Importance: High

Good morning,

Please see the response below that Eric provided to Rep. Foster's office.

Thanks,
Holly

Holly G. Williams, MPA
(O) 404-639-0318
(M) 404-295-9574
Telework Fridays

From: Wortman, Eric (CDC/OD/CDCWO)
Sent: Wednesday, October 3, 2018 3:51 PM
To: Williams, Holly G. (CDC/OPHPR/OD) <wwf7@cdc.gov>; Dills, Kimberly C. (ATSDR/OPPE) <kid4@cdc.gov>; Protzel Berman, Pamela (CDC/ONDIEH/NCEH) <pxp5@cdc.gov>
Subject: FW: air sampling user guide

FYI – below is our response to Foster's office. After much deliberation (b)(5)

(b)(5)

Eric

From: Wortman, Eric (CDC/OD/CDCWO)
Sent: Wednesday, October 3, 2018 3:48 PM
To: 'Warren, Samantha' **Cc:** Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>; Timmins, Gary
Subject: RE: air sampling user guide

Hi, Samantha –

I'm sorry for the delay in getting back to you on this. We've been carefully considering the request. Estimation of the number of cancer cases associated with the levels found in the community surrounding the Sterigenics facility would be highly uncertain.

However, the Cancer Registry program at the Illinois Department of Public Health is conducting a review of cancer incidence within the census tracts surrounding the Sterigenics facility. A cancer incidence analysis only determines whether there is an increase in observed cancer in a specific area compared to the expected cancer. This type of ecologic analysis is not intended to nor is it able to determine an exposure-response relationship. A full epidemiological investigation (e.g. case-control study) would need to be conducted in order to determine any exposure-response relationship. Per the CDC/CSTE guidelines, a cancer incidence analysis can be used as a first step to determine if a more in-depth investigation into cancer rates is warranted.

Please let us know if you have any further questions,

Eric

Eric Wortman
CDC Washington
Phone: 202-245-0616

EXHIBIT I

From: Johnson, Mark
Sent: 20 Sep 2018 21:47:06 +0000
To: 'Mumtaz, Moiz (ATSDR/DTHHS/OD)';mkj5@cdc.gov
Subject: RE: Asking for an opinion
Attachments: Sterigenics ATSDR Public Statement- FINAL 8-27-18.pdf

Moiz

Good to hear from you. Wish it was something less controversial.

We have been working on the Sterigenics investigation for several months with EPA. We posted the ATSDR Health Consultation document on our website on Aug. 21st. It was a very technical document that was written to inform and support an enforcement decision by EPA- R5 against Sterigenics to reduce their emissions of ethylene oxide (EtO). Unfortunately, EPA HQs did not allow for the implementation of the communications strategy that we had planned with EPA-R5. As a result, our Health Consultation document was the only communication to the public, which was not the intended audience. The outcome was the generation of a great deal of concern among workers in the nearby commercial buildings and nearby residents. We had a very contentious public meeting on Aug. 29th, with 500 people in attendance. We are in the process of preparing a summary fact sheet and a technical document for the public.

To respond to the questions from your friend- We have provided a clarifying statement to the Village of Willowbrook (see attached), which they have posted on their website, stating that this is not an immediate health threat and is not an emergency situation. The health concerns are with long-term exposure to EtO in the community. In last July, Sterigenics implemented engineering controls to reduce their emissions of EtO. They are conducting stack tests today and tomorrow to verify the extent of emissions reductions. At this point we do not think that it is unsafe to work and live in the area. Feel free to provide your friend with my contact information (mdjohnson@cdc.gov;312-353-3436) and we can try to answer any other questions he may have.

Mark

Mark D. Johnson, PhD, DABT
Regional Director/Toxicologist
Agency for Toxic Substances and Disease Registry (ATSDR)
77 W. Jackson Blvd. Rm. 433
Chicago, IL 60604
Email: mdjohnson@cdc.gov
Office: 312-353-3436
Cell: 312-307-7415

EXHIBIT J

Agency for Toxic Substances and Disease Registry (ATSDR) Statement about the Letter Health Consultation *"Evaluation of Potential Health Impacts for Ethylene Oxide Emissions"*

The Agency for Toxic Substances and Disease Registry (ATSDR) on August 21, 2018, released a Letter Health Consultation report, *"Evaluation of Potential Health Impacts for Ethylene Oxide Emissions,"* in relation to the Sterigenics International, Incorporated facility in Willowbrook, IL. Sterigenics uses ethylene oxide to sterilize medical equipment and other products. ATSDR prepared the report at the request of the U.S. Environmental Protection Agency-Region 5, and posted the findings on the ATSDR website to share with the public.

The emissions of ethylene oxide from the Sterigenics International, Inc. facility in Willowbrook, IL **are not an immediate threat to public health and are not considered to be an emergency situation**. ATSDR recommended to U.S. EPA that actions be taken to reduce emissions of ethylene oxide from this facility to protect the public from long-term exposures that could harm their health.

The conclusion in the ATSDR Letter Health Consultation report,

> *"If measured and modeled data represent typical EtO ambient concentrations in ambient air, an elevated cancer risk exists for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These evaluated risks present a public health hazard to these populations"*

is to inform and support the regulatory decisions being made by the state and EPA to reduce emissions from that facility to protect public health.

ATSDR based this conclusion on estimated cancer risks that are calculated using conservative assumptions about a lifetime exposure to the highest levels of ethylene oxide that were measured in Willowbrook commercial and residential areas near the facility. The highest measured levels of ethylene oxide in those areas were about 1,000 times lower than levels associated with cancer risks in scientific studies of workers with industrial exposure to EtO.

U.S. EPA has been working with Illinois EPA and Sterigenics to reduce emissions of ethylene oxide from the company's facility. In July 2018, the company installed additional pollution controls to capture ethylene oxide emissions. U.S. EPA and Illinois EPA will monitor the effectiveness of the new equipment to determine whether any other actions are needed to protect public health.

EXHIBIT K

Office: 312-353-3436
Cell: 312-307-7415

From: Johnson, Mark
Sent: Monday, August 27, 2018 4:47 PM
To: 'ftrilla@willowbrook.il.us' <ftrilla@willowbrook.il.us>;
'lissa@serafin.com' <lissa@serafin.com>
Cc: Michelle Colledge <Colledge.Michelle@epa.gov>
Subject: ATSDR statement about the Health Consultation for the Sterigenics facility

Mayor Trilla

Here is the statement that we have been working on at CDC/ATSDR to provide some additional context for the public regarding the Health Consultation document for the Sterigenics facility in Willowbrook. As mentioned in the statement, this was a technical document that was intended to inform and support regulatory agency actions by USEPA and Illinois EPA to reduce emissions from this facility, rather than a direct communication to the general public.

Hopefully, this statement will clarify some aspects of our report. Feel free to use the information as you find beneficial to your community. We are committed to answering any health-related questions from your office and from residents of Willowbrook.

Mark

Note: you may notice that you are receiving this from an EPA email address. However, we are not part of EPA, but lease computer server space from EPA. You can send emails to either my CDC account (mdjohnson@cdc.gov) or EPA account (johnson.mark@epa.gov).

Mark D. Johnson, PhD, DABT
Regional Director/Toxicologist
Agency for Toxic Substances and Disease Registry (ATSDR)
77 W. Jackson Blvd. Rm. 433
Chicago, IL 60604
Email: mdjohnson@cdc.gov
Office: 312-353-3436
Cell: 312-307-7415

The content image001.jpg of type has been blocked.

EXHIBIT L

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 27, 2018

OFFICE OF
AIR AND RADIATION

The Honorable Richard Durbin
United States Senate
Washington, D.C. 20510

Dear Senator Durbin:

Thank you for your letter of September 21, 2018, about ethylene oxide emissions from the Sterigenics facility in Willowbrook, Illinois. Please know that the Agency shares your concerns and is taking actions to provide certainty to the residents of Willowbrook. In the short term, the U.S. Environmental Protection Agency's (EPA) national Office of Air and Radiation will be collecting, analyzing, and communicating technical information, including recent stack testing results, risk and exposure modeling, and ambient monitoring, to provide updated, comprehensive information to the public. It is important to note that the air concentrations of ethylene oxide are not high enough to cause immediate harm to health for the people in and around Willowbrook.

We are working with state and local air agencies and other EPA offices to take steps to address emissions of ethylene oxide, and are committed to continuing to provide information to the public throughout this process. Initial information, including links to information for the Willowbrook facility, is available on our ethylene oxide website at: https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide.

Willowbrook is one of a number of areas that the recently updated National Air Toxics Assessment (NATA) identifies as potentially having an elevated chronic risk from ethylene oxide. NATA is a screening tool to identify areas of the country, pollutants or types of pollution sources that may need to be examined further to better understand risks to public health. Ethylene oxide is used to sterilize equipment and plastic devices that cannot be sterilized by steam, such as medical equipment. The elevated risks from ethylene oxide in the 2014 NATA are driven largely by a toxicity value from the Agency's 2016 IRIS assessment, which estimated that ethylene oxide is 50 to 60 times more potent than previous estimates. This value is used along with the information about air concentrations (exposure), to determine potential risk of cancer that may occur to someone who is continuously exposed to a specific chemical for 24 hours per day over 70 years.

Over the last several months, EPA has provided ethylene oxide-related information from NATA and additional technical work to the community in and around Willowbrook. We know that this information has raised a number of questions and the Agency is working to develop additional technical and communication materials to help the community understand the potential risks.

Based on preliminary NATA results earlier this year, EPA Region 5 contacted Sterigenics about its emissions. The company quickly and voluntarily took steps to reduce emissions using pollution control equipment. The pollution control improvements were completed on July 27, 2018. Sterigenics had estimated that the control equipment would reduce ethylene oxide emissions by over 90 percent. After the pollution controls began operating, a contractor hired by Sterigenics conducted stack testing of ethylene oxide emissions at the facility on September 20 and 21, 2018. U.S. EPA subject matter experts as well as experts from the Illinois EPA were on site to ensure that the tests followed EPA-approved protocols and would provide the right type of information to inform the community about resulting changes in emissions and concentrations of ethylene oxide. This testing will give the Agency the information it needs to provide the most accurate picture of the potential risks to the community, and actions the Agency may need to take.

We expect to receive the results of the testing in the next few days. Early indications from the post-control stack testing suggest that emissions have indeed been significantly reduced. Our experts will work with our colleagues at the Illinois EPA to review the test data as soon as we receive it to quality assure the results and make them available to the public as expeditiously as possible. EPA will use the quality-assured data from the stack tests to conduct additional technical assessments that will help us estimate potential risk for the community. U.S. EPA will work closely with Illinois EPA and Sterigenics as we conduct these assessments.

We have received a number of requests to conduct outdoor air quality monitoring of ethylene oxide in Willowbrook. While there are limitations to the ability of currently available monitoring instruments and techniques to measure ethylene oxide at all levels that may present a long-term public health risk, EPA also intends to supplement this technical work with appropriate ambient monitoring in the near future. It is important to note that data from emissions testing at the stack provides the most accurate information to assist us in determining potential risk.

EPA is also working to further investigate emissions at the other areas NATA indicated may be at higher risk due to ethylene oxide exposure. We will work with state and local agencies and across EPA offices on a two-pronged approach to address ethylene oxide emissions:

1. The Agency has already started to review and update Clean Air Act regulations for facilities that emit ethylene oxide. This work includes standards applicable to chemical plants that use ethylene oxide and, more importantly for Willowbrook, standards for sterilizers that use ethylene oxide.

2. We are gathering additional information on industrial emissions of ethylene oxide from particular facilities, including the Willowbrook facility. This information will help EPA as it evaluates opportunities to reduce ethylene oxide emissions as part of its regulations review. It also will help the Agency determine whether more immediate emission reduction steps are necessary in any particular locations.

Additional information on our work to address ethylene oxide is available at: https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide. The 2014 NATA results are available at: https://www.epa.gov/national-air-toxics-assessment/2014-nata-assessment-results.

EPA will continue to coordinate closely with state and local air agencies, and across EPA offices, as we continue to work to address ethylene oxide and protect public health across the U.S. Please do not hesitate to contact me or Troy Lyons in the Office of Congressional and Intergovernmental Relations at lyons.troy@epa.gov or 202-564-5200 if you wish to discuss this issue further.

Sincerely,

William L. Wehrum
Assistant Administrator

EXHIBIT M

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 27, 2018

OFFICE OF
AIR AND RADIATION

The Honorable Tammy Duckworth
United States Senate
Washington, D.C. 20510

Dear Senator Duckworth:

Thank you for your letter of September 21, 2018, about ethylene oxide emissions from the Sterigenics facility in Willowbrook, Illinois. Please know that the Agency shares your concerns and is taking actions to provide certainty to the residents of Willowbrook. In the short term, the U.S. Environmental Protection Agency's (EPA) national Office of Air and Radiation will be collecting, analyzing, and communicating technical information, including recent stack testing results, risk and exposure modeling, and ambient monitoring, to provide updated, comprehensive information to the public. It is important to note that the air concentrations of ethylene oxide are not high enough to cause immediate harm to health for the people in and around Willowbrook.

We are working with state and local air agencies and other EPA offices to take steps to address emissions of ethylene oxide, and are committed to continuing to provide information to the public throughout this process. Initial information, including links to information for the Willowbrook facility, is available on our ethylene oxide website at: https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide.

Willowbrook is one of a number of areas that the recently updated National Air Toxics Assessment (NATA) identifies as potentially having an elevated chronic risk from ethylene oxide. NATA is a screening tool to identify areas of the country, pollutants or types of pollution sources that may need to be examined further to better understand risks to public health. Ethylene oxide is used to sterilize equipment and plastic devices that cannot be sterilized by steam, such as medical equipment. The elevated risks from ethylene oxide in the 2014 NATA are driven largely by a toxicity value from the Agency's 2016 IRIS assessment, which estimated that ethylene oxide is 50 to 60 times more potent than previous estimates. This value is used along with the information about air concentrations (exposure), to determine potential risk of cancer that may occur to someone who is continuously exposed to a specific chemical for 24 hours per day over 70 years.

Over the last several months, EPA has provided ethylene oxide-related information from NATA and additional technical work to the community in and around Willowbrook. We know that this information has raised a number of questions and the Agency is working to develop additional technical and communication materials to help the community understand the potential risks.

Based on preliminary NATA results earlier this year, EPA Region 5 contacted Sterigenics about its emissions. The company quickly and voluntarily took steps to reduce emissions using pollution control equipment. The pollution control improvements were completed on July 27, 2018. Sterigenics had estimated that the control equipment would reduce ethylene oxide emissions by over 90 percent. After the pollution controls began operating, a contractor hired by Sterigenics conducted stack testing of ethylene oxide emissions at the facility on September 20 and 21, 2018. U.S. EPA subject matter experts as well as experts from the Illinois EPA were on site to ensure that the tests followed EPA-approved protocols and would provide the right type of information to inform the community about resulting changes in emissions and concentrations of ethylene oxide. This testing will give the Agency the information it needs to provide the most accurate picture of the potential risks to the community, and actions the Agency may need to take.

We expect to receive the results of the testing in the next few days. Early indications from the post-control stack testing suggest that emissions have indeed been significantly reduced. Our experts will work with our colleagues at the Illinois EPA to review the test data as soon as we receive it to quality assure the results and make them available to the public as expeditiously as possible. EPA will use the quality-assured data from the stack tests to conduct additional technical assessments that will help us estimate potential risk for the community. U.S. EPA will work closely with Illinois EPA and Sterigenics as we conduct these assessments.

We have received a number of requests to conduct outdoor air quality monitoring of ethylene oxide in Willowbrook. While there are limitations to the ability of currently available monitoring instruments and techniques to measure ethylene oxide at all levels that may present a long-term public health risk, EPA also intends to supplement this technical work with appropriate ambient monitoring in the near future. It is important to note that data from emissions testing at the stack provides the most accurate information to assist us in determining potential risk.

EPA is also working to further investigate emissions at the other areas NATA indicated may be at higher risk due to ethylene oxide exposure. We will work with state and local agencies and across EPA offices on a two-pronged approach to address ethylene oxide emissions:

1. The Agency has already started to review and update Clean Air Act regulations for facilities that emit ethylene oxide. This work includes standards applicable to chemical plants that use ethylene oxide and, more importantly for Willowbrook, standards for sterilizers that use ethylene oxide.

2. We are gathering additional information on industrial emissions of ethylene oxide from particular facilities, including the Willowbrook facility. This information will help EPA as it evaluates opportunities to reduce ethylene oxide emissions as part of its regulations review. It also will help the Agency determine whether more immediate emission reduction steps are necessary in any particular locations.

Additional information on our work to address ethylene oxide is available at: https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide. The 2014 NATA results are available at: https://www.epa.gov/national-air-toxics-assessment/2014-nata-assessment-results.

EPA will continue to coordinate closely with state and local air agencies, and across EPA offices, as we continue to work to address ethylene oxide and protect public health across the U.S. Please do not hesitate to contact me or Troy Lyons in the Office of Congressional and Intergovernmental Relations at lyons.troy@epa.gov or 202-564-5200 if you wish to discuss this issue further.

Sincerely,

William L. Wehrum
Assistant Administrator

EXHIBIT N

DECLARATION OF Teleflex Medical

I, Gregg Twomey, declare as follows:

1. I am the Director of Global Procurement of Teleflex Medical ("Teleflex"). The matters set forth below are within my personal knowledge, and if called upon as a witness, I could and would testify competently as to each of them.

2. Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care.

3. Teleflex uses the Willowbrook, Illinois sterilization facility (the "Willowbrook Facility") of Sterigenics, U.S., LLC ("Sterigenics"), to sterilize certain of its products.

4. On an annual basis, approximately 7 million units of Teleflex products are sterilized at the Willowbrook Facility.

5. The unplanned shutdown of the WillowBrook Facility will impact Teleflex's ability to supply hospitals and healthcare providers with the products described above. Specifically, the shutdown will require Teleflex to work with customers to identify alternative products that can be used as substitutes for those sterilized at the Willowbrook Facility. Assuming suitable substitute products are identified, our ability to provide such products on a timely basis will depend on current inventory levels of such substitute products, as well as the location of such inventory. In the event suitable substitute products cannot be identified, those products will be unavailable to customers until Teleflex is able to identify and qualify an alternative sterilization facility for those products.

6. I declare under penalty of perjury that the foregoing is true and correct.

Executed on the 7th day of March, 2019, in Teleflex Global Operations Headquarters, Ireland

Gregg Twomey
Director Global Procurement

EXHIBIT O

10-K 1 a2018form10-k.htm 10-K FY2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934, or**
For the fiscal year ended December 31, 2018

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
Commission File No. 1-11083

BOSTON SCIENTIFIC CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE	**04-2695240**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

300 BOSTON SCIENTIFIC WAY, MARLBOROUGH, MASSACHUSETTS 01752-1234
(Address of principal executive offices) (zip code)
(508) 683-4000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

COMMON STOCK, $.01 PAR VALUE PER SHARE	**NEW YORK STOCK EXCHANGE**
(Title of each class)	(Name of exchange on which registered)

Securities registered pursuant to Section 12(g) of the Act:
NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes: ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes: ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes: ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorted period that the registrant was required to submit such files). Yes: ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑	Accelerated filer ☐	Non-accelerated filer ☐
Smaller reporting company ☐	Emerging growth company ☐	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes: ☐ No ☑

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

The aggregate market value of the registrant's common stock held by non-affiliates was approximately $45.0 billion based on the last reported sale price of $32.70 of the registrant's common stock on the New York Stock Exchange on June 29, 2018, the last business day of the registrant's most recently completed second fiscal quarter. (For this computation, the registrant has excluded the market value of all shares of common stock of the registrant reported as beneficially owned by executive officers, and directors of the registrant; such exclusion shall not be deemed to constitute an admission that any such person is an affiliate of the registrant.)

The number of shares outstanding of the registrant's common stock as of January 31, 2019 was 1,385,961,926.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission in connection with its 2019 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

TABLE OF CONTENTS

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

PART I

ITEM 1. BUSINESS

Our Company

Boston Scientific Corporation is a global developer, manufacturer and marketer of medical devices that are used in a broad range of interventional medical specialties. Our mission is to transform lives through innovative medical solutions that improve the health of patients around the world. As a medical technology leader for nearly 40 years, we advance science for life by providing a broad range of high performance solutions to address unmet patient needs and reduce the cost of healthcare. When used in this report, the terms "we," "us," "our" and "the Company" mean Boston Scientific Corporation and its divisions and subsidiaries.

Our history began in the late 1960s when our co-founder, John Abele, acquired an equity interest in Medi-tech, Inc., a research and development company focused on developing alternatives to surgery. In 1969, Medi-tech introduced a family of steerable catheters used in some of the world's first less-invasive procedures. In 1979, John Abele joined with Pete Nicholas to form Boston Scientific Corporation, which indirectly acquired Medi-tech. This acquisition began a period of active and focused new product development, innovation, market development and organizational growth. Since then, we have advanced the practice of less-invasive medicine by helping physicians and other medical professionals diagnose and treat a wide range of diseases and medical conditions and improve patients' quality of life by providing alternatives to surgery and other medical procedures that are typically traumatic to the body.

Our net sales have increased substantially since our formation. Our growth has been fueled in part by strategic acquisitions designed to improve our ability to take advantage of growth opportunities in the medical device industry and to build depth of portfolio within our core businesses. These strategic acquisitions have helped us to add promising new technologies to our pipeline and to offer one of the broadest product portfolios in the world for use in less-invasive procedures in our core areas of Medical Surgical (MedSurg), Rhythm and Neuro, and Cardiovascular. We believe that the depth and breadth of our product portfolio has also enabled us to compete more effectively in the current healthcare environment that seeks to improve outcomes and lower costs. Our strategy of category leadership also enables us to compete in a changing, contracting landscape and position our products with physicians, managed care, large buying groups, governments and hospitals, while also expanding internationally and managing the complexities of the global healthcare market.

Business Strategy

We operate pursuant to five strategic imperatives: Strengthen Category Leadership, Expand into High Growth Adjacencies, Drive Global Expansion, Fund the Journey to Fuel Growth and Develop Key Capabilities. We believe that our execution of these strategic imperatives will drive innovation, accelerate profitable revenue growth and increase stockholder value while strengthening our leadership position in the medical device industry.

We expect to continue to invest in our core franchises and pursue opportunities to diversify and further expand our presence in strategic growth adjacencies and new global markets. Our approach to innovation combines internally-developed products and technologies with those we may obtain externally through strategic acquisitions, alliances and other investments. Our research and development efforts are focused largely on the development of next-generation and novel technology offerings across multiple programs and divisions. In the past several years, we have completed numerous acquisitions in support of our growth strategy, both strengthening our core franchises and expanding into high growth adjacent markets.

Our Enterprise Risk Management program analyzes the key risks inherent to achieving our strategic and organizational imperatives. Such risk assessment helps us to anticipate and adapt to potential challenges to preserve and grow shareholder value. Our Board of Directors oversees our risk management program and focuses on the most significant risks facing the Company, including strategic, operational, financial, legal and compliance risks.

Products

In 2018, our products were offered for sale by seven core businesses: Interventional Cardiology, Cardiac Rhythm Management, Endoscopy, Urology and Pelvic Health, Peripheral Interventions, Neuromodulation and Electrophysiology. In 2018, our revenue was comprised of 26 percent from our Interventional Cardiology business, 20 percent from our Cardiac Rhythm Management business, 18 percent from our Endoscopy business, 13 percent from our Urology and Pelvic Health business, 12 percent from our Peripheral Interventions business, eight percent from our Neuromodulation business and three percent from our Electrophysiology business.

Our seven core businesses are organized into three reportable segments: MedSurg, Rhythm and Neuro, and Cardiovascular. Effective January 1, 2018, following organizational changes to align the structure of our business with our focus on active implantable devices, we revised our reportable segments, in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 280, *Segment Reporting*. The revision reflects a reclassification of our Neuromodulation business from our Medical Surgical (MedSurg) segment to our newly created Rhythm and Neuro segment. We have revised prior year amounts to conform to the current year's presentation (as denoted with an asterisk (*) throughout). There was no revision to operating segments or reporting units as a result of the organizational change.

The following describes our principal product offerings by reportable segment.

MedSurg

Endoscopy

Gastroenterology and Pulmonary

Our Endoscopy business develops and manufactures devices to diagnose and treat a broad range of gastrointestinal (GI) and pulmonary conditions with innovative, less invasive technologies. Our product offerings include:

- our SpyGlass™ DS System, which brings digital imaging, a wider field of view and a simpler set-up (compared to our legacy SpyGlass System), thus enabling cholangioscopy to play a greater role in the diagnosis and treatment of pancreatico-biliary diseases,
- our Resolution 360™ Clip, a hemostatic clipping technology designed to stop and help prevent bleeding during endoscopic procedures,
- our Epic™ Biliary Endoscopic Stent System, indicated for the palliation of malignant strictures, is our first laser cut self-expanding metal stent and complements our braided metal stent portfolio,
- our Acquire™ Endoscopic Ultrasound Fine Needle Biopsy Device, which is designed to obtain larger tissue specimens for histological assessment and is useful when diagnosing diseases such as pancreatic cancer, liver cancer and stomach lesions,
- our AXIOS™ Stent and Electrocautery Enhanced Delivery System, the first, and currently only, stent in the U.S. indicated for endoscopic drainage of pancreatic pseudocysts,
- our infection prevention portfolio, which includes a customizable Compliance EndoKit™ and single-use Orca™ Valves, designed to minimize the risk of infection transmission and improve operational efficiencies by streamlining manual cleaning or eliminating the need for cleaning and tracking, and
- our endoluminal surgery portfolio with ORISE™ Tissue Retractor System, designed to enable tissue retraction and countertraction during en bloc colonic tissue resection procedures and ORISE™ Gel, designed to be used for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions prior to excision with a snare or other endoscopic device.

Urology and Pelvic Health

Our Urology and Pelvic Health business develops and manufactures devices to treat various urological and pelvic conditions for both male and female anatomies, including kidney stones, benign prostatic hyperplasia (BPH), prostate cancer, erectile dysfunction, male incontinence, pelvic floor disorders, abnormal uterine bleeding and uterine fibroids and polyps. Our product offerings include:

- a full line of stone management products, including ureteral stents, catheters, baskets, guidewires, sheaths and balloons and stone laser devices,
- our LithoVue™ Single-Use Digital Flexible Ureteroscope, which delivers detailed high-resolution digital images for high-quality visualization and seamless navigation,
- penile implants to treat erectile dysfunction and urinary control systems to treat male urinary incontinence, under our Men's Health portfolio,
- our GreenLight XPS™ Laser System, our MoXy™ Fiber and our newly acquired Rezūm™ System, purchased as part of the NxThera, Inc. (NxThera) acquisition in the second quarter of 2018, under our BPH therapies,
- a range of devices for the treatment of Women's Health conditions such as stress urinary incontinence, pelvic organ prolapse, heavy menstrual bleeding (menorrhagia) and uterine fibroids and polyps and

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

- our SpaceOAR™ Hydrogel System, purchased as part of the Augmenix, Inc. (Augmenix) transaction in the fourth quarter of 2018, to help reduce side effects that men may experience after receiving radiotherapy to treat prostate cancer.

Rhythm and Neuro

Cardiac Rhythm Management

Our Cardiac Rhythm Management (CRM) business develops and manufactures a variety of implantable devices that monitor the heart and deliver electricity to treat cardiac abnormalities. Our product offerings include:

- our implantable cardioverter defibrillators (ICD) and implantable cardiac resynchronization therapy defibrillators (CRT-D) as well as the world's first, and currently only, commercially available subcutaneous implantable cardiac defibrillators (S-ICD),
- our pacemakers and implantable cardiac resynchronization therapy pacemakers (CRT-P) and
- our LATITUDE™ Remote Patient Management System, which allows for more frequent monitoring and better guided treatment decisions by enabling physicians in most geographies to monitor implantable system performance remotely.

Our entire transvenous defibrillator portfolio leverages our EnduraLife™ Battery Technology, including our extended longevity (EL) ICD, our CRT-D's and our MINI (smallest and thinnest) ICD.

Our most current generation of defibrillators, the RESONATE™ family of devices, is available in most major markets around the world. These devices include our proprietary HeartLogic™ Heart Failure (HF) Diagnostic, EnduraLife Battery Technology and SmartCRT™ with Multisite pacing in CRT-D. Magnetic resonate imaging (MRI) conditional labeling, which was approved by the U.S. Food and Drug Administration (FDA) in September 2017 and launched in the fourth quarter of 2017, covers our current generation RESONATE family of devices, as well as our prior generation of DYNAGEN™ and INOGEN™ devices. We have MRI conditional labeling across our defibrillator portfolio in most major markets around the world, when used with our current generation of leads. Our implantable defibrillator portfolio is complemented by our suite of ACUITY™ X4 Quadripolar LV Leads, RELIANCE™ family of ICD Leads and INGEVITY™ Pacing Lead.

In addition to our transvenous defibrillator portfolio, we offer our EMBLEM™ MRI S-ICD System, which provides physicians the ability to treat patients who are at risk for sudden cardiac arrest without touching the heart or invading the vasculature. Our EMBLEM S-ICD devices have MRI conditional labeling and LATITUDE Remote Patient Management in most major markets.

We market our ACCOLADE™ family of pacemaker systems in nearly all major markets around the world. Approval of our ACCOLADE Pacemaker family in the U.S., Europe and Japan also included approval for use of these products in patients undergoing MRI scans. We received FDA approval of our ACCOLADE™ MRI-Compatible Pacemaker and MRI-compatible INGEVITY™ Pacing Lead in April 2016. Much like our defibrillator portfolio, our pacemakers leverage our INGEVITY Pacing Leads and LATITUDE™ Remote Patient Management in nearly all major markets.

Electrophysiology

Our Electrophysiology business develops and manufactures less-invasive medical technologies used in the diagnosis and treatment of rate and rhythm disorders of the heart, including a broad portfolio of therapeutic and diagnostic catheters and a variety of equipment used in the Electrophysiology lab. Our product offerings include:

- our Rhythmia™ Mapping System, a next-generation, catheter-based, 3-D cardiac mapping and navigation solution designed to help diagnose and guide treatment of a variety of arrhythmias,
- our Blazer™ Therapeutic Ablation Catheter line,
- a broad portfolio of diagnostic catheters including Blazer™ Dx-20, Dynamic Tip™ and Viking™ Catheters,
- intracardiac ultrasound catheters, delivery sheaths and other accessories and
- a full offering of capital equipment used in Electrophysiology labs, such as recording systems, generators and pumps.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Our cooled ablation catheter portfolio includes our U.S. and CE Mark approved Blazer™ Open-Irrigated, IntellaNav™ Open-Irrigated, and IntellaNav MiFi™ Open-Irrigated ablation catheters with a unique Total Tip Cooling™ Design. We also offer our IntellaNav™ XP and IntellaNav™ MiFi XP solid tip catheters. Our IntellaTip™ MiFi XP, IntellaNav™ MiFi XP and IntellaNav™ MiFi Open-Irrigated Catheters include MicroFidelity (MiFi) sensor technology in the catheter tip. All of our IntellaNav Catheters are designed to allow magnetic tracking when used with our Rhythmia Mapping System.

Our capital equipment offerings include our Rhythmia Mapping System, LabSystem™ PRO Recording System, Maestro™ RF Generators and the MetriQ™ Pump. In 2015, the Rhythmia Mapping System and IntellaMap Orion™ Mapping Catheter began full global commercialization, bringing to market a next-generation system capable of high-density high-resolution mapping. We are now in full global commercialization of our next generation Rhythmia HDx™ Mapping System.

Neuromodulation

Our Neuromodulation business develops and manufactures devices to treat various neurological movement disorders and manage chronic pain. Our product offerings include:

- our Precision™, Precision Spectra™, Precision Montage™, Precision Novi™ and Spectra WaveWriter™ Spinal Cord Stimulator (SCS) Systems, designed to provide improved pain relief to a wide range of patients who suffer from chronic pain and
- our Vercise™, Vercise™ PC and Vercise Gevia™ Deep Brain Stimulation (DBS) Systems for the treatment of Parkinson's disease, tremor, and intractable primary and secondary dystonia, a neurological movement disorder characterized by involuntary muscle contractions.

The Precision Spectra SCS System is the world's first and only SCS system with 32 contacts and 32 dedicated power sources. We believe that we continue to have a technological advantage due to our proprietary features such as Multiple Independent Current Control and our Illumina 3D™ Proprietary Programming Software, which together are intended to allow the physician to target specific areas of pain and customize stimulation of nerve fibers more precisely. In 2015, we launched the Precision Novi SCS System in Europe and then in the U.S., offering the smallest 16-contact high capacity primary cell (PC) device, also referred to as non-rechargeable. In 2016, we launched the Precision Montage SCS System in Europe and the U.S. offering a 16-contact rechargeable system with Illumina 3D programming and full body MRI labeling when conditions of use are met. In January 2018, we announced FDA approval for the Spectra WaveWriter SCS System, the first and only system approved by the FDA to simultaneously provide paresthesia-based and sub-perception therapy.

In 2018, we began commercializing our Vercise™ DBS System in the U.S. following FDA approval in late 2017. The Vercise DBS System is approved in the U.S. as an adjunctive therapy that aids in reducing some of the symptoms of moderate to advanced Parkinson's disease. We also have regulatory approval for our Vercise DBS System in various international regions including Europe, Latin America and Asia Pacific. Our Vercise Gevia™ DBS System with the Cartesia™ Directional Lead is the first and only MRI conditional, rechargeable and directional system, using multi-directional stimulation designed for greater precision, intended to minimize side effects for patients. The Cartesia Directional Lead continues to expand our market access in Europe, Japan and various countries in Latin America. In January 2019, Vercise Gevia DBS System with the Cartesia Directional Lead was approved by the FDA. In the third quarter of 2018, we received CE mark approval in Europe for GUIDE™ XT System, the first DBS visualization system built for directionality that utilizes patient specific anatomy and stimulation field modeling. This technology provides physicians with 3-D image planning capability and when used in conjunction with the Vercise DBS Systems, enables physicians to personalize and optimize DBS treatment.

Cardiovascular

Interventional Cardiology

Our Interventional Cardiology business develops and manufactures technologies for diagnosing and treating coronary artery disease and other cardiovascular disorders including structural heart conditions. Our broad, innovative product offerings have led to our leadership in the global interventional cardiology market.

Drug-Eluting Coronary Stent Systems

Our drug-eluting coronary stent product offerings are an important element of our global Interventional Cardiology market leadership. We believe we have enhanced the outcomes associated with the use of coronary stents, particularly the processes that lead to restenosis (the growth of neointimal tissue within an artery after angioplasty and stenting), through our scientific research and product development of drug-eluting stent systems. Our coronary stent offerings include:

- our SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System, featuring an ultra-thin abluminal (outer) bioabsorbable polymer coating,
- our Promus ELITE™ Everolimus-Eluting Stent and
- our Promus PREMIER™ and Promus™ Element™ Everolimus-Eluting family of Stents.

Complex PCI Therapies

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Our product offerings to perform complex percutaneous coronary interventions (PCI) include a broad line of products used to treat patients with atherosclerosis, a principal cause of coronary artery obstructive disease. These include balloon catheters,

rotational atherectomy systems, guide wires, guide catheters, embolic protection devices, crossing and re-entry devices for the treatment of chronically occluded coronary vessels and diagnostic catheters used in percutaneous transluminal coronary angioplasty (PTCA) procedures.

PCI Guidance

Our PCI Guidance offerings include a family of intravascular catheter-directed ultrasound imaging catheters, complemented by our intravascular ultrasound (IVUS) imaging system and our fractional flow reserve (FFR) devices and systems for use in coronary arteries and heart chambers as well as certain peripheral vessels to assist in the diagnosis of coronary artery disease. Our PCI Guidance product offerings include:

- our OptiCross™ IVUS Imaging catheter,
- our COMET™ FFR Pressure Guidewire and
- our iLab™ Ultrasound Imaging System with Polaris Software, designed to enhance the diagnosis and treatment of blocked vessels and other heart disorders, which is compatible with our full line of imaging catheters and FFR devices and continues to be our flagship console.

The iLab Ultrasound Imaging System has been placed in cardiology labs worldwide and provides an installed base through which we expect to continue to sell associated single-use products.

Structural Heart Therapies

Structural heart therapy is one of the fastest growing areas of the medical technology market and is highly synergistic with our Interventional Cardiology and Rhythm Management businesses. Our current structural heart product offerings include:

- our WATCHMAN™ Left Atrial Appendage Closure (LAAC) Technology (WATCHMAN), designed to close the left atrial appendage in patients with non-valvular atrial fibrillation who are at risk for ischemic stroke,
- our ACURATE TA™, ACURATE *neo*™, ACURATE *neo2*™ and ACURATE TF™ Aortic Valve Systems, which are based on a self-expanding architecture and
- our Sentinel™ Cerebral Embolic Protection System, purchased as part of our acquisition of Claret Medical, Inc. (Claret) in the third quarter of 2018.

WATCHMAN is the first device to offer a non-pharmacologic alternative to warfarin that has been studied in a randomized clinical trial and is marketed globally. The WATCHMAN device has been commercially available internationally since 2009, received FDA approval in 2015 and is the leading device in percutaneous LAAC globally. We believe that the WATCHMAN device will be the only LAAC technology commercially available in the U.S. for multiple years.

In addition, the Lotus EDGE™ Valve System is a TAVR product based on a mechanically-expanded architecture. It is an investigational device within our structural heart portfolio and is not currently commercially available. We submitted the Premarket Approval (PMA) application for the Lotus EDGE Aortic Valve System in the second half of 2018 which included the filing of the final technical module. Our goal is to return the Lotus EDGE Valve System to market in 2019.

Peripheral Interventions

Our Peripheral Interventions business develops and manufactures products to diagnose and treat peripheral arterial diseases, including a broad line of medical devices used in percutaneous transluminal angioplasty (PTA) and peripheral vascular diseases, as well as products to diagnose, treat and ease various forms of cancer. Our broad peripheral product offerings include products to treat arterial diseases (stents, balloon catheters, wires and atherectomy) and venous diseases (thrombectomy, wires and stents) and employ interventional oncology techniques to treat various cancers (peripheral embolization devices, microcatheters and drainage catheters).

Our peripheral angioplasty balloon technologies include:

- our Mustang™ PTA next-generation Balloon Catheter, a 0.035" balloon with superior crossing and tracking, powerful dilatation, longer lengths and smaller sheath sizes,

- our Coyote™ Balloon Catheter, a highly deliverable and ultra-low profile balloon dilatation catheter designed for a wide range of peripheral angioplasty procedures and
- our Sterling™ Balloon Catheter, a 0.018" PTA balloon catheter designed for post-stent dilatation as well as conventional balloon angioplasty to open blocked peripheral arteries.

Our peripheral stent technologies include:

- our EPIC™ Vascular Self-Expanding Stent System, a nitinol stent designed to sustain vessel patency while providing enhanced visibility and accuracy during placement,
- our Innova™ Self-Expanding Stent System, a laser-cut nitinol stent built for the superficial femoral artery (SFA, a large artery in the thigh) with flexibility, strength and fracture resistance and
- our Eluvia™ Drug Eluting Vascular Stent System, an innovative stent built on the Innova stent platform, designed to deliver a sustained dosage of paclitaxel during the time when restenosis is most likely to occur.

We received FDA approval for the Eluvia Drug-Eluting Vascular Stent System in the third quarter of 2018 and previously received a CE Mark approval in February 2016.

Our venous disease technologies include:

- our AngioJet™ Thrombectomy System, used in endovascular procedures to remove blood clots from blocked arteries and veins,
- our AngioJet Zelante DVT™ Thrombectomy Catheter to treat deep vein thrombosis (DVT) in large-diameter upper and lower limb peripheral veins, in the U.S. and Europe and
- our VICI VENOUS STENT™ System to treat venous obstructive disease, which was purchased as part of the VENITI, Inc. acquisition in the third quarter of 2018.

We also offer products designed to treat patients with non-vascular disease, primarily in interventional oncology. Our product offerings in this area include:

- our Direxion™ Torqueable Microcatheter and
- our line of interventional oncology product solutions, including the Renegade™ HI-FLO™ Fathom™ Microcatheter and Guidewire System and Interlock™ - 35 Fibered IDC™ and 18 Fibered IDC™ Occlusion System for peripheral embolization.

Proposed BTG Acquisition

On November 20, 2018, our board of directors and the board of directors of our wholly owned indirect subsidiary, Bravo Bidco Limited (Bidco), and BTG plc (BTG), a public company organized under the laws of England and Wales, issued an announcement (the Rule 2.7 Announcement) under Rule 2.7 of the United Kingdom City Code on Takeovers and Mergers, disclosing the terms of a recommended cash offer to be made by Bidco for the entire issued and to be issued ordinary share capital of BTG (the proposed BTG Acquisition). On January 24, 2019, Bidco made such offer on the terms and subject to the conditions of the scheme document published on the same date. In connection with the proposed BTG Acquisition, (i) we entered into a co-operation agreement with Bidco and BTG, (ii) certain shareholders and each BTG director owning shares of BTG delivered deeds of irrevocable undertakings to Bidco and (iii) we entered into a bridge credit agreement (the Bridge Facility). Refer to *Note E – Borrowings and Credit Arrangements* to our consolidated financial statements contained in Item 8. Financial Statements and Supplementary Data of this Annual Report for further details of the Bridge Facility. On February 14, 2019, each of the Company and BTG received a request for additional information and documentary material from the United States Federal Trade Commission in connection with the proposed BTG Acquisition.

Under the terms of the proposed BTG Acquisition, BTG shareholders will receive 840 pence in cash for each BTG share, which values BTG's existing issued and to be issued ordinary share capital at approximately £3.311 billion (or approximately $4.225 billion based on the exchange rate of U.S. $1.28: £1.00 on December 31, 2018). We intend to implement the proposed BTG Acquisition by way of a court-sanctioned scheme of arrangement (Scheme) under Part 26 of the United Kingdom Companies Act 2006, as amended (the Companies Act).

BTG develops and commercializes products used in minimally-invasive procedures targeting cancer and vascular diseases, as well as acute care pharmaceuticals.

The proposed BTG Acquisition will be subject to conditions and certain further terms, including (i) the approval of the Scheme by a majority in number of BTG shareholders also representing not less than 75 percent in value of the BTG shares, in each case, present, entitled to vote and voting, (ii) the sanction of the Scheme by the High Court of Justice in

England and Wales, (iii) the Scheme becoming effective no later than August 20, 2019 and (iv) the receipt of regulatory approvals. The conditions to the proposed BTG Acquisition are set out in full in the Rule 2.7 Announcement. Subject to the satisfaction or waiver of all relevant

conditions, we expect the proposed BTG Acquisition to be effective in the first half of 2019. Refer to *Note B – Acquisitions and Strategic Investments* to our consolidated financial statements contained in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional details related to the proposed BTG Acquisition.

Research and Development

Our investment in research and development is critical to driving our future growth. Our investment in research and development supports the following:

- internal research and development programs, regulatory design and clinical science, as well as other programs obtained through our strategic acquisitions and alliances and
- engineering efforts that incorporate customer feedback into continuous improvement efforts for currently marketed and next-generation products.

We have directed our development efforts toward innovative technologies designed to expand current markets or enter adjacent markets. We are transforming how we conduct research and development and are scrutinizing our cost structure, which we believe will enable increased development activity and faster concept-to-market timelines.

Focused, cross-functional teams take a formal approach to new product design and development, helping us to manufacture and offer innovative products consistently and efficiently. Involving cross-functional teams early in the process is the cornerstone of our product development cycle. We believe this collaboration allows our teams to concentrate resources on the most viable and clinically relevant new products and technologies and maximize cost and time savings as we bring them to market.

In addition to internal development, we work with hundreds of leading research institutions, universities and clinicians around the world to develop, evaluate and clinically test our products. We are expanding our collaborations to include research and development teams in emerging markets; these teams will focus on both global and local market requirements at a lower cost of development. We believe that these efforts will play a significant role in our future success.

Marketing and Sales

In 2018, we marketed our products and solutions to approximately 35,000 hospitals, clinics, outpatient facilities and medical offices in the U.S. and in approximately 130 countries worldwide. The majority of our net sales are derived from countries in which we have direct sales organizations. We also have a network of distributors and dealers who offer our products in certain countries and markets. We expect to continue to leverage our infrastructure in markets where commercially appropriate and use third party distributors in those markets where it is not economical or strategic to establish or maintain a direct presence.

No single institution accounted for more than ten percent of our net sales in 2018, 2017 or 2016; however, large group purchasing organizations, hospital networks and other buying groups have become increasingly important to our business and represent a substantial portion of our net sales. We have a dedicated corporate accounts organization in the U.S. and Europe focused principally on selling to major buying groups and integrated healthcare networks. We consistently strive to understand and exceed the expectations of our customers. Each of our businesses maintains dedicated sales forces and marketing teams focused on physicians who specialize in the diagnosis and treatment of different medical conditions, as well as on key hospital service line administrators. We believe that this dual focus on disease state management and hospital administrators enables us to develop highly knowledgeable and dedicated sales representatives and to foster collaborative relationships with both physicians and key service line administrators. We believe that our positive working relationships with physicians, service line administrators and others in the medical industry enable us to gain a detailed understanding of new therapeutic and diagnostic alternatives and to respond quickly to our customers' changing needs.

International Operations

International net sales accounted for 44 percent of our net sales in 2018 and 43 percent of our net sales in both 2017 and 2016. Maintaining and expanding our international presence is an important component of our long-term growth strategy. Through our international presence, we seek to increase net sales and market share, leverage our relationships with leading physicians and their clinical research programs, accelerate the time to bring new products to market and gain access to worldwide technological developments that we can implement across our product lines. In addition, we are investing in infrastructure in emerging markets to strengthen our sales and service capabilities and maximize our opportunities in these countries.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

As of December 31, 2018, we had nine principal international manufacturing facilities, including three in Ireland, two in Costa Rica, one in Brazil, one in Malaysia, one in Puerto Rico and one in Switzerland. Approximately 45 percent of our products

manufactured in 2018 were produced at these facilities. We also maintain research and development capabilities in China, Costa Rica, Germany, India, Ireland and Puerto Rico. We operate physician training centers in China, France, Germany, India, Italy, Japan, Poland, South Africa and South Korea.

Manufacturing and Raw Materials

We are focused on continuously improving our supply chain effectiveness, strengthening our manufacturing processes and increasing operational efficiencies within our organization. We strive to improve the efficiency of our sourcing operations and to leverage the technical expertise of the broader market by partnering with strategic suppliers. In doing so, we seek to focus our internal resources on the development and commercial launch of new products and the enhancement of existing products. We continue to implement new systems designed to provide improved quality, reliability, service, greater efficiency and lower supply chain costs. We also drive continuous improvement in product quality through process controls and validations, supplier and distribution controls and providing our operations teams with the necessary training and tools. In addition, we remain focused on examining our operations and general business activities to enhance our operational effectiveness by identifying cost-improvement opportunities.

We remain committed to maintaining prudent investments in supply chain resiliency on an ongoing basis. Our products are designed and manufactured in technology centers around the world, either by us or third parties. We consistently monitor our inventory levels, manufacturing and distribution capabilities and maintain recovery plans to address potential disruptions that we may encounter. Many components used in the manufacturing of our products are readily fabricated from commonly available raw materials or off-the-shelf items available from multiple supply sources; however, certain items are custom made to meet our specifications. We believe that in most cases, redundant capacity exists at our suppliers and that alternative sources of supply are available or could be developed within a reasonable period of time. We also have an ongoing program to identify single-source components and to develop alternative back-up supplies and we regularly readdress the adequacy and abilities of our suppliers to meet our needs.

Quality Assurance

We are committed to providing high quality products to our customers. Our quality system starts with the initial product specification and continues through the design of the product, component specification process and the manufacturing, sale and servicing of the product. Our quality system is intended to build in quality and process control and to utilize continuous improvement concepts throughout the product life. These systems are designed to enable us to satisfy various international quality system regulations, including those of the FDA with respect to products sold in the U.S. All of our manufacturing facilities and distribution centers are certified under the ISO 13485 quality system standard, established by the International Standards Organization (ISO) for medical devices, which includes requirements for an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. This certification can be obtained only after a complete audit of a company's quality system by an independent outside auditor. Maintenance of the certification requires that these facilities undergo periodic re-examination.

Environmental Regulation and Management

We are subject to various environmental laws, directives and regulations both in the U.S. and abroad. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe that sound environmental, health and safety performance contributes to our competitive strength while benefiting our customers, stockholders and employees. We are focused on continuous improvement in these areas by reducing pollution, depletion of natural resources and our overall environmental footprint. Specifically, we are working to optimize energy and resource usage, ultimately reducing greenhouse gas emissions and waste. We are listed on the FTSE4Good Corporate Social Responsibility Index, managed by the Financial Times and the London Stock Exchange, which measures the performance of companies that meet globally recognized standards of corporate responsibility. This listing recognizes our dedication to those standards and it places us in a select group of companies with a demonstrated commitment to responsible business practices and sound environmental policies.

We have obtained ISO 14001:2015 certifications at our major manufacturing plants and Tier 1 distribution centers around the world, as well as our Corporate headquarters in Marlborough, Massachusetts. ISO 14001:2015 is a globally recognized standard for Environmental Management Systems, established by the International Standards Organization, which provides a voluntary framework to identify key environmental aspects associated with our business. Using this environmental management system and the specific attributes of our certified locations in the U.S., Ireland, Costa Rica and the Netherlands, we continue to improve our environmental performance and reduce our environmental footprint.

Competition

We encounter significant competition across our product lines and in each market in which we sell our products and solutions, some from companies that may have greater financial and marketing resources than we do. Our primary competitors include Abbott Laboratories, Medtronic plc and Cook Medical, as well as a wide range of medical device companies that sell a single or limited number of competitive products or participate in only a specific market segment. We also face competition from non-medical device companies, such as pharmaceutical companies, which may offer alternative therapies for disease states that could also be treated using our products.

We believe that our products and solutions compete primarily on their ability to deliver both clinical and economic outcomes for our customers while also continuing to perform diagnostic and therapeutic procedures safely and effectively in a less-invasive manner. We also compete on ease of use, comparative effectiveness, reliability and physician familiarity. In the current environment of managed care, with economically-motivated buyers, consolidation among healthcare providers, increased competition and declining reimbursement rates, we have been increasingly required to compete on the basis of price, value, reliability and efficiency. We believe the current global economic conditions and healthcare reform measures could continue to put additional competitive pressure on us, including on our average selling prices, overall procedure rates and addressable market sizes. We recognize that our continued competitive success will depend upon our ability to:

- offer products and solutions that provide differentiated clinical and economic outcomes,
- create or acquire innovative, scientifically advanced technologies,
- apply our technology and solutions cost-effectively and with superior quality across product lines and markets,
- develop or acquire proprietary products and solutions,
- attract and retain skilled personnel,
- obtain patent or other protection for our products,
- obtain required regulatory and reimbursement approvals,
- continually enhance our quality systems,
- manufacture and successfully market our products and solutions either directly or through outside parties and
- supply sufficient inventory to meet customer demand.

Medical Device Regulatory Approvals

The medical devices that we manufacture and market are subject to regulation by numerous worldwide regulatory bodies, including the FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing development, testing, manufacturing, labeling, marketing and distribution. Medical devices are also generally subject to varying levels of regulatory control based on risk level of the device.

In the U.S., authorization to distribute a new device can generally be met in one of three ways. The first process requires that a premarket notification (510(k)) be made to the FDA to demonstrate that the device is as safe and effective as, or substantially equivalent to, a legally marketed device (the "predicate" device). Applicants must submit performance data to establish substantial equivalence. In some instances, data from human clinical trials must also be submitted in support of a 510(k) premarket notification. If so, these data must be collected in a manner that conforms to the applicable Investigational Device Exemption (IDE) regulations. The FDA must issue a decision finding substantial equivalence before commercial distribution can occur. Changes to cleared devices that could not significantly affect the safety or effectiveness of the device can generally be made without additional 510(k) premarket notifications; otherwise, a new 510(k) is required.

The second process requires the submission of a premarket approval (PMA) application to the FDA to demonstrate that the device is safe and effective for its intended use. This approval process applies to most Class III devices and generally requires clinical data to support the safety and effectiveness of the device, obtained in adherence with IDE requirements. The FDA will approve the PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose and that the proposed manufacturing is in compliance with the Quality System Regulation (QSR). For novel technologies, the FDA will generally seek input from an advisory panel of medical experts and seek their views on the safety, effectiveness and benefit-risk of the device. The PMA process is generally more detailed, lengthier and more expensive than the 510(k) process.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

The third process requires that an application for a Humanitarian Device Exemption (HDE) be made to the FDA for the use of a Humanitarian Use Device (HUD). An HUD is intended to benefit patients by treating or diagnosing a disease or condition that affects, or is manifested in, not more than 8,000 individuals in the U.S. per year. The application submitted to the FDA for an HDE is similar in both form and content to a PMA application, but is exempt from the effectiveness requirements of a PMA. The HUD

provision of the regulation provides an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting smaller patient populations.

In the European Economic Area (EEA), we are required to comply with applicable Medical Device Directives, specifically the Medical Devices Directive and the Active Implantable Medical Device Directive. These directives require us to affix a CE Mark on medical devices prior to placing them on the market within the EEA. The CE Mark is affixed following conformity assessment and either approval from the appointed independent Notified Body or through self-certification by the manufacturer. The selected pathway to CE marking is based on product risk. CE Marking indicates conformity to the applicable Essential Requirements of the relevant Medical Devices Directive. The European Union (EU) Commission published a new Medical Device Regulation in 2017, providing a three-year transition period until May 2020, at which time, the existing Directives will be repealed. The Medical Device Regulation will change multiple aspects of the existing regulatory framework, such as higher clinical evidence requirements and introduce several new requirements, such as Unique Device Identification (UDI) and many other post-market obligations. Thus, the new Medical Device Regulation significantly modifies and intensifies the compliance requirements for the industry.

We are also required to comply with the regulations of every other country where we commercialize products before we can launch or maintain new products on the market, such as the requirement that we obtain approval from the Japanese Ministry of Health, Labor and Welfare (MHLW), the Japanese Pharmaceutical & Medical Device Agency (PMDA) and the China Food and Drug Administration (NMPA). Many countries that previously did not have medical device regulations, or minimal regulations, are now introducing them. For example, India is in the process of expanding its current regulations to include all medical device categories while many countries in the Middle East and Southeast Asia are introducing new regulations.

The FDA and other worldwide regulatory agencies and competent authorities actively monitor compliance to local laws and regulations through review and inspection of design and manufacturing practices, record keeping, reporting of adverse events, labeling and promotional practices. The FDA can ban certain medical devices, detain or seize adulterated or misbranded medical devices, order repair, replacement or refund of these devices and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain a company for certain violations of the Food, Drug and Cosmetic Act and the Safe Medical Devices Act pertaining to medical devices or initiate action for criminal prosecution of such violations. Regulatory agencies and authorities in the countries where we do business can halt production in or distribution within their respective country or otherwise take action in accordance with local laws and regulations.

International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or that are banned or deviate from lawful performance standards, are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. due to differing regulatory requirements; however, other countries, such as China for example, require approval in the country of origin first. Most countries outside of the U.S. require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and, where needed, conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

Government Affairs

We maintain a global Government Affairs presence, headquartered in Washington, D.C., to actively monitor and advocate on a myriad legislation and policies impacting us, both on a domestic and an international front. The Government Affairs office works closely with members of Congress and committee staff, the White House and Administration offices, state Governors, legislatures and regulatory agencies, embassies and global governments on issues affecting our business. Our proactive approach and depth of political and policy expertise are aimed at having our positions heard by federal, state and global decision-makers to improve patient care and to advance our business objectives by educating policymakers on our positions, key priorities and the value of our technologies. The Government Affairs office also manages our political action committee and works closely with trade groups on issues affecting our industry and healthcare in general.

Healthcare Policies and Reimbursement

Political, economic and regulatory influences around the world continue to subject the healthcare industry to potential fundamental changes that could substantially affect our results of operations. Government and private sector initiatives related to limiting the growth of healthcare costs (including price regulation), coverage and payment policies,

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

comparative effectiveness reviews of therapies, technology assessments and health care delivery structure reforms, are continuing in many countries where we do

business. We believe that these changes are causing the marketplace to put increased emphasis on the delivery of treatments that can reduce costs, improve efficiencies and/or increase patient access. Although we believe our less-invasive products and technologies generate favorable clinical outcomes, value and cost efficiency, the resources necessary to demonstrate value to our customers, patients, payers and other stakeholders are significant and new therapies now take longer periods of time to gain widespread adoption.

The impact to our business of the U.S. Patient Protection and Affordable Care Act's (ACA) provisions related to coverage expansion, payment reforms and delivery system has been immaterial. The ACA and Health Care and Education Affordability Reconciliation Act were enacted into law in the U.S. in 2010. The legislation imposed on medical device manufacturers a 2.3 percent excise tax on U.S. sales of Class I, II and III medical devices beginning in January 2013. In December 2015, the Promise for Antibiotics and Therapeutics for Health Act, or PATH Act, was passed, which included legislation which temporarily suspended the 2.3 percent excise tax until December 31, 2017. In January 2018, another temporary two-year suspension of the 2.3 percent excise tax was passed, extending the suspension to December 31, 2019. We have reinvested substantial amounts of funds that we would have expended on this tax into jobs, innovation, research and development, collaborations with universities and other initiatives that will help treat patients and drive revenue growth.

The U.S. Federal government, as part of the ACA, and certain state governments have enacted laws aimed at increasing transparency, or "sunshine," in relationships between medical device, biologics and pharmaceutical companies and healthcare professionals (HCPs). As a result, we are required by law to report many types of payments and transfers of value provided to HCPs. Certain foreign jurisdictions are currently acting to implement similar laws. Failure to comply with sunshine laws and/or implement and adhere to adequate policies and practices to address changes to legal and regulatory requirements could have a negative impact on our results of operations. Additional legislation at the state and federal levels may result in further changes to these laws.

As noted below, we expect certain trends to continue placing pressure on pricing and utilization in the U.S. The Tax Cuts and Jobs Acts (TCJA), enacted December 22, 2017 in the U.S., makes changes to the tax treatment of health care expenses and repealed the “individual mandate” to purchase private insurance. These tax law changes have resulted in changes to insurance coverage and financing of insurance coverage in individual markets. Additional legislation may result in changes to government programs such as Medicare and Medicaid. In addition, the current U.S. Administration has enacted a number of administrative policy changes that will likely result in additional changes to insurance coverage, financing of insurance coverage and benefits offered through private insurance in both the employer-sponsored and individual markets. These changes and other similar changes being considered are likely to lead to an increase in the number of people without insurance. Other individual coverage policies will be less generous than those required under the ACA. The impact of these changes on coverage levels and patient cost-sharing could affect utilization of non-urgent, non-acute services in which our devices are used.

Additionally, while the implementation of the medical device tax has further been suspended until December 31, 2019, the status of the tax for sales after December 31, 2019 is not clear. The medical device tax may continue to be suspended, or it may be reinstated at the same or at a different level effective January 1, 2020.

We expect that pricing of medical devices will remain under pressure as alternative payment reform, such as prospective payment systems for hospital care, preferential site of service payments, value-based purchasing and accountable care organizations (ACOs), continue to take shape globally. We also expect marketplace changes to place pressure on medical device pricing globally as hospitals consolidate and large group purchasing organizations, hospital networks and other groups continue to seek to aggregate purchasing power. Similarly, governments are increasing the use of tenders, placing pressure on medical device pricing. Some governments also seek to limit the growth of healthcare costs through price regulation. Implementation of cost containment initiatives and healthcare reforms in significant markets such as the U.S., Japan and Europe and other markets may limit the price of, or the level at which reimbursement is provided for, our products, which in turn may influence a hospital’s or physician's selection of products used to treat patients.

Our products are purchased principally by hospitals, physicians and other healthcare providers around the world that typically bill various third-party payers, including government programs (e.g., Medicare and Medicaid in the U.S.) and private insurance payers, for the services provided to their patients. Third-party payers and governments may approve or deny coverage for certain technologies and associated procedures based on independently determined assessment criteria. Coverage decisions by payers for these technologies and associated procedures are based on a wide range of methodologies that may reflect the assessed resource costs, clinical outcomes and economic value of the technologies and associated procedures.

Proprietary Rights and Patent Litigation

We rely on a combination of patents, trademarks, trade secrets and other forms of intellectual property to protect our proprietary rights. We generally file patent applications in the U.S. and foreign countries where patent protection for our technology is appropriate and available. As of December 31, 2018, we held more than 19,000 patents and had approximately 5,000 patent applications pending worldwide that cover various aspects of our technology. In addition, we hold exclusive and non-exclusive licenses to a variety of third-party technologies covered by patents and patent applications. In the aggregate, these intellectual property assets and licenses are of material importance to our business; however, we believe that no single patent, technology, trademark, intellectual property asset or license is material in relation to our business as a whole.

We rely on non-disclosure and non-competition agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry, particularly in the areas in which we compete. We continue to defend ourselves against claims and legal actions alleging infringement of the patent rights of others. Additionally, we may find it necessary to initiate litigation to enforce our patent rights, to protect our trade secrets or know-how and to determine the scope and validity of the proprietary rights of others. Accordingly, we may seek to settle some or all of our pending litigation, particularly to manage risk over time. Settlement may include cross licensing of the patents that are the subject of the litigation as well as our other intellectual property and may involve monetary payments to or from third parties.

We maintain insurance policies providing limited coverage against securities claims. We are substantially self-insured with respect to product liability claims and fully self-insured with respect to intellectual property infringement claims. The absence of significant third-party insurance coverage increases our potential exposure to unanticipated claims or adverse decisions. See *Note J – Commitments and Contingencies* to our 2018 consolidated financial statements included in Item 8 of this Annual Report for a discussion of intellectual property, product liability and other litigation and proceedings in which we are involved.

Employees

As of December 31, 2018, we had approximately 32,000 employees, including approximately 15,000 in operations, 10,000 in selling, marketing and distribution, 5,000 in clinical, regulatory and research and development and 4,000 in administration. Of these employees, we employed approximately 17,000 outside the U.S., approximately 10,000 of whom are in the manufacturing operations function.

Community Outreach

We are united by a goal to make a difference in the lives of the 30 million patients we serve. We envision what is possible for communities around the world by giving our time and resources to positively impact the lives of others. Guided by our core values, we seek to improve access to healthcare, to invest in educational programming for students with limited means and access to opportunities, and to support and embrace the spirit of volunteerism within our global workforce, while adhering to strong ethical standards. We also recognize the need to minimize the impact of the manufacturing of our products on the environment and have committed to carbon neutrality in our manufacturing and key distribution sites by 2030.

In some parts of the world, access to health information, screening, care and services can be limited. We have partnered with Project HOPE (Health Opportunities for People Everywhere) and Partners in Health to increase the number of healthcare workers in South Africa, India and Mexico. By increasing the number and proficiency of community healthcare workers, we can impact health outcomes for people today and into the future. In 2018, we added to our list of Global Health Grantees by supporting the Children's HeartLink (CHL) team based in Malaysia. During the year, CHL began formal collaboration with the Malaysian Pediatric Cardiac Society (MPCS) to increase access to high quality pediatric cardiac care for all children in Malaysia. All of our Global Health grants aim to increase the number of healthcare workers, increase screening and awareness about non-communicable diseases, provide an opportunity for our local in-country teams to get involved with our grantees and align with the United Nations Sustainable Development Goal Number Three - *GOOD HEALTH AND WELL-BEING: Ensuring healthy lives and promoting the well-being for all at all ages is essential to sustainable development.*

We are also inspired by young learners who share our passion for innovation and problem solving. Our employees work with students around the world and share their passion for Science, Technology, Engineering and Math (STEM) through participation in more than 200 STEM events and school programs. Beyond the classroom, our employees provided more than 43,000 hours of community service to make a positive impact at more than 600 global community events in 33 countries. Building on our culture of caring, in 2017, we

created an Employee Disaster Relief Fund to support families impacted by large natural weather events and disasters. In 2018, many families impacted by Hurricane Maria continued to benefit from resources from this fund, with our employees and the Company donating nearly $1 million dollars to the fund. In addition, we hosted six employee fundraising

campaigns to support other natural disasters that impacted people around the world. More than 200 employees contributed to these campaigns, which was combined with a Company match and funds donated to the various charitable organizations in support of disaster relief efforts.

We also support the five U.S. communities where we have significant business presences through the Boston Scientific Foundation. The mission of the foundation is simple: to help expand access to quality health care and educational opportunities for underserved populations. The Boston Scientific Foundation awarded nearly $1 million dollars in grant awards to more than 50 nonprofit organizations across the U.S. in 2018. The process involved more than 65 employee volunteers who evaluated proposals for the Boston Scientific Foundation Board review and approval, upon which the Boston Scientific Foundation was able to help fuel grassroots innovative solutions to improve access to quality healthcare and create new opportunities for students to learn and achieve.

Seasonality

Our net sales are influenced by many factors, including product launches, acquisitions, regulatory and reimbursement approvals, patient, physician and employee holiday schedules and other macro-economic conditions. While our net sales do not reflect any significant degree of seasonality, customer purchases have historically been lower in the first and third quarters of the year.

Available Information

Copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act), are available free of charge on our website (www.bostonscientific.com) as soon as reasonably practicable after we electronically file the material with or furnish it to the U.S. Securities and Exchange Commission (SEC). Additionally, the SEC maintains an internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Printed copies of these posted materials are also available free of charge to stockholders who request them in writing from Investor Relations, 300 Boston Scientific Way, Marlborough, MA 01752-1234. Information on our website or linked to our website is not incorporated by reference into this Annual Report.

Safe Harbor for Forward-Looking Statements

Certain statements that we may make from time to time, including statements contained in this Annual Report and information incorporated by reference into this Annual Report, constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend," "aiming" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements.

The forward-looking statements in this Annual Report are based on certain risks and uncertainties, including the risk factors described in Item 1A under the heading "Risk Factors" and the specific risk factors discussed below and in connection with forward-looking statements throughout this Annual Report, which could cause actual results to vary materially from the expectations and projections expressed or implied by our forward-looking statements. These risks and uncertainties, in some cases, have affected and in the future could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this Annual Report. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements. Risks and uncertainties that may cause such differences include, among other things: future economic, political, competitive, reimbursement and regulatory conditions, new product introductions and the market acceptance of those products, markets for our products, expected pricing environment, expected procedural volumes, the closing and integration of acquisitions, clinical trial results, demographic trends, intellectual property rights, litigation, financial market conditions, the execution and effect of our restructuring program, the execution and effect of our business strategy, including our cost-savings and growth initiatives and future business decisions made by us and our competitors. New risks and uncertainties may arise from time to time and are difficult to predict. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Item 1A. Risk Factors contained within this Annual Report on Form 10-K filed with the SEC, which we may update in Part II, Item 1A. Risk Factors in subsequent Quarterly Reports on Form 10-Q that we will file hereafter. We disclaim any intention or obligation to publicly update or revise any

forward-looking statement to reflect any change in our expectations or in events, conditions, or circumstances on which those expectations may be based, or that may affect the likelihood

that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this Annual Report.

The following are some of the important risk factors that could cause our actual results to differ materially from our expectations in any forward-looking statements. For further discussion of these and other risk factors, see Item 1A. Risk Factors.

Our Businesses

- Our ability to increase net sales, expand the market, capture market share and adapt to market volatility,
- The ongoing impact on our business of physician alignment to hospitals, governmental investigations and audits of hospitals and other market and economic conditions on the overall number of procedures performed,
- Competitive offerings and related declines in average selling prices for our products,
- The performance of, and physician and patient confidence in, our products and technologies or those of our competitors,
- The impact and outcome of ongoing and future clinical trials and market studies undertaken by us, our competitors or other third parties or perceived product performance of our or our competitors' products,
- Variations in clinical results, reliability or product performance of our and our competitors' products,
- Our ability to acquire or develop, launch and supply new or next-generation products and technologies worldwide and in line with our commercialization strategies in a timely and successful manner and with respect to our recent acquisitions,
- The effect of consolidation and competition in the markets in which we do business or plan to do business,
- Disruption in the manufacture or supply of certain components, materials or products, or the failure to secure in a timely manner alternative manufacturing or additional or replacement components, materials or products,
- Our ability to retain and attract key personnel,
- The impact of enhanced requirements to obtain regulatory approval in the U.S. and around the world, including the associated timing and cost of product approval, and
- The impact of increased pressure on the availability and rate of third-party reimbursement for our products and procedures in the U.S. and around the world, including with respect to the timing and costs of creating and expanding markets for new products and technologies.

Regulatory Compliance, Litigation and Data Protection

- The impact of healthcare policy changes and legislative or regulatory efforts in the U.S., the EU and around the world to modify product approval or reimbursement processes, including a trend toward demonstrating clinical outcomes, comparative effectiveness and cost efficiency, as well as the impact of other healthcare reform legislation,
- Risks associated with our regulatory compliance and quality systems and activities in the U.S., the EU and around the world, including meeting regulatory standards applicable to manufacturing and quality processes,

- Our ability to minimize or avoid future field actions or FDA warning letters relating to our products and processes and the ongoing inherent risk of potential physician advisories related to medical devices,

- The impact of increased scrutiny of and heightened global regulatory enforcement facing the medical device industry arising from political and regulatory changes, economic pressures or otherwise, including under U.S. Anti-Kickback Statute, U.S. False Claims Act and similar laws in other jurisdictions, U.S. Foreign Corrupt Practices Act (FCPA) and similar laws in other jurisdictions, and U.S. and foreign export control, trade embargo and customs laws,

- Costs and risks associated with litigation,

- The effect of our litigation and risk management practices, including self-insurance and compliance activities on our loss contingencies, legal provision and cash flows,
- The impact of, diversion of management attention as a result of, and costs to cooperate with, litigate and/or resolve governmental investigations and our class action, product liability, contract and other legal proceedings,
- The possibility of failure to protect our intellectual property rights and the outcome of patent litigation, and
- Our ability to properly operate our information systems that support our business operations and protect our data integrity and products from a cyber-attack or other breach that has a material adverse effect on our business, reputation or results of operations.

Innovation and Certain Growth Initiatives

- The timing, size and nature of our strategic growth initiatives and market opportunities, including with respect to our internal research and development platforms and externally available research and development platforms and technologies and the ultimate cost and success of those initiatives and opportunities,
- Our ability to complete planned clinical trials successfully, obtain regulatory approvals and launch new and next generation products in a timely manner consistent with cost estimates, including the successful completion of projects from in-process research and development,
- Our ability to identify and prioritize our internal research and development project portfolio and our external investment portfolio on profitable revenue growth opportunities as well as to keep them in line with the estimated timing and costs of such projects and expected revenue levels for the resulting products and technologies,
- Our ability to successfully develop, manufacture and market new products and technologies in a timely manner and the ability of our competitors and other third parties to develop products or technologies that render our products or technologies noncompetitive or obsolete,
- Our ability to execute appropriate decisions to discontinue, write-down or reduce the funding of any of our research and development projects, including projects from in-process research and development, in our growth adjacencies or otherwise,
- Our dependence on acquisitions, alliances or investments to introduce new products or technologies and to enter new or adjacent growth markets and our ability to fund them or to fund contingent payments with respect to those acquisitions, alliances and investments, and
- The potential failure to successfully integrate and realize the expected benefits from the strategic acquisitions, alliances and investments we have consummated or may consummate in the future.

International Markets

- Our dependency on international net sales to achieve growth, including in emerging markets,
- The impact of changes in our international structure and leadership,
- The timing and collectability of customer payments,
- The political and economic conditions (including the impact of the United Kingdom's exit from the EU, often referred to as "Brexit"),
- Protection of our intellectual property,

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

- Our ability to comply with established and developing U.S. and foreign legal and regulatory requirements, including FCPA and similar laws in other jurisdictions
- Our ability to comply with U.S. and foreign export control, trade embargo and custom laws,

- The impact of changes in reimbursement practices and policies in both the U.S. and abroad,
- Our ability to maintain or expand our worldwide market positions in the various markets in which we compete or seek to compete, including through investments in product diversification and emerging markets such as Brazil, Russia, India and China,
- Our ability to execute and realize anticipated benefits from our investments in emerging markets, and
- The potential effect of foreign currency fluctuations and interest rate fluctuations on our net sales, expenses and resulting margins.

Liquidity

- Our ability to generate sufficient cash flow to fund operations, capital expenditures, global expansion initiatives, any litigation settlements and judgments, share repurchases and strategic investments and acquisitions as well as maintaining our investment grade ratings and managing our debt levels and covenant compliance,
- Our ability to access the public and private capital markets when desired and to issue debt or equity securities on terms reasonably acceptable to us,
- The unfavorable resolution of open tax matters, exposure to additional tax liabilities and the impact of changes in U.S. and international tax laws,
- The impact of examinations and assessments by domestic and international taxing authorities on our tax provision, financial condition or results of operations,
- The possibility of counterparty default on our derivative financial instruments,
- The impact of potential intangible asset impairment charges, including on our results of operations, and
- Our ability to collect outstanding and future receivables and/or sell receivables under our factoring programs.

Cost Reduction and Optimization Initiatives

- Risks associated with significant changes made or expected to be made to our organizational and operational structure, pursuant to our restructuring plans as well as any further restructuring or optimization plans we may undertake in the future and our ability to recognize benefits and cost reductions from such programs and
- Business disruption and employee distraction as we execute our global compliance program, restructuring and optimization plans and divestitures of assets or businesses and implement our other strategic and cost reduction initiatives.

ITEM 1A. RISK FACTORS

In addition to the other information contained in this Annual Report and the exhibits hereto, the following risk factors should be considered carefully in evaluating our business. Our business, financial condition, cash flows or results of operations could be materially adversely affected by any of these risks. This section contains forward-looking statements. You should refer to the explanation of the qualifications and limitations on forward-looking statements set forth at the end of Item 1. Business of this Annual Report. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business, financial condition, cash flows or results of operations.

We face intense competition and may not be able to keep pace with the rapid technological changes in the medical devices industry, which could have an adverse effect on our business, financial condition or results of operations.

The medical device markets in which we primarily participate are highly competitive. We encounter significant competition across our product lines and in each market in which our products are sold from various medical device companies. Some of our competitors may have greater financial and marketing resources than we do, including as a result of consolidation among companies in our industry. Our primary competitors include Abbott Laboratories, Medtronic plc and Cook Medical, as well as a wide range of medical device companies that sell a single or limited number of competitive products or which participate in only a specific market segment or set of segments. We also face competition from non-medical device companies, including pharmaceutical companies, which may offer alternative therapies for disease states also amenable to treatment using our products. New direct or indirect competitors may emerge in the future, potentially including companies introducing new sales or distribution models to our industry.

In addition, the medical device markets in which we primarily participate are characterized by extensive research and development and rapid technological change. Developments by other companies of products and/or services, processes or technologies may make our products or proposed products obsolete or less competitive and may negatively impact our net sales. It is necessary for us to devote continued efforts and financial resources to the development or acquisition of scientifically advanced technologies and products. In addition, we will need to apply our technologies cost-effectively across product lines and markets, obtain patent and other protection for our technologies and products, obtain required regulatory and reimbursement approvals and successfully manufacture and market our products consistent with our quality standards. If we fail to develop or acquire new products or enhance existing products, such failure could have a material adverse effect on our business, financial condition or results of operations. In addition, a delay in the timing of the launch of next-generation products and the overall performance of, and continued physician confidence in, those products may result in declines in our market share and have an adverse impact on our business, financial condition or results of operations.

We may experience declines in market size, average selling prices for our products, medical procedure volumes and our share of the markets in which we compete, which may materially adversely affect our results of operations and financial condition.

We continue to experience pressures across many of our businesses due to competitive activity, increased market power of our customers as the healthcare industry consolidates, economic pressures experienced by our customers and the impact of managed care organizations and other third-party payers. These and other factors may adversely impact market sizes, as well as our share of the markets in which we compete, the average selling prices for our products or medical procedure volumes. There can be no assurance that the size of the markets in which we compete will increase above existing levels, that we will be able to regain or gain market share or compete effectively on the basis of price or that the number of procedures in which our products are used will increase above existing levels. Decreases in market sizes or our market share and declines in average selling prices or procedural volumes could materially adversely affect our results of operations or financial condition.

Continued consolidation in the healthcare industry or additional governmental controls exerted over pricing in key markets could lead to increased demands for price concessions or limit or eliminate our ability to sell to certain of our significant market segments, which could have an adverse effect on our business, financial condition or results of operations.

Numerous initiatives and reforms by legislators, regulators and third-party payers to curb the rising cost of healthcare have catalyzed a consolidation of aggregate purchasing power within the markets in which we sell our products. As the healthcare industry consolidates, competition to provide products and services is expected to continue to intensify, resulting in pricing pressures, decreased average selling prices and the exclusion of certain suppliers from important market segments. We expect that market demand, government regulation, third-party coverage and reimbursement policies, government contracting requirements and societal pressures will continue to change the worldwide healthcare industry,

resulting in further business consolidations and alliances among our customers, which may increase competition, exert further downward pressure on the prices of our products and services and may adversely impact our business, financial condition or results of operations.

Healthcare cost containment pressures, government payment and delivery system reforms, changes in private payer policies, and marketplace consolidations could decrease the demand for our products, the prices which customers are willing to pay for those products and/or the number of procedures performed using our devices, which could have an adverse effect on our business, financial condition or results of operations.

Our products are purchased principally by hospitals, physicians and other healthcare providers around the world that typically bill various third-party payers, including government programs, authorities or agencies (e.g., Medicare and Medicaid in the United States) and private health plans, for the healthcare services provided to their patients. Governments and payers may also institute changes in healthcare delivery systems that may reduce funding for services or encourage greater scrutiny of health care costs. The ability of customers to obtain appropriate reimbursement for their products and services from private and governmental third-party payers is critical to the success of medical technology companies because it affects which products customers purchase and the prices they are willing to pay. Reimbursement and funding vary by country and can significantly impact the acceptance of new products and technologies and the use of established products and technologies. Even if we develop a promising new product, we may find limited demand for the product unless reimbursement approval is obtained from private and governmental third-party payers. Further legislative or administrative reforms to the reimbursement systems in the U.S., Japan, or other countries in a manner that significantly reduces reimbursement for procedures using our medical devices or denies coverage for those procedures, including price regulation, competitive bidding and tendering, coverage and payment policies, comparative effectiveness of therapies, heightened clinical data requirements, technology assessments and managed-care arrangements, could have a material adverse effect on our business, financial condition or results of operations

We are subject to a number of market, business, financial, legal and regulatory risks and uncertainties with respect to our international operations that could have a material impact on our business, financial condition or results of operations.

International net sales accounted for 44 percent of our global net sales in 2018, which includes sales from emerging markets accounting for approximately 11 percent. An important part of our strategy is to continue pursuing growth opportunities in net sales and market share outside of the U.S. by expanding global presence, including in emerging markets. Our international operations are subject to a number of market, business and financial risks and uncertainties, including those related to geopolitical and economic instability, foreign currency exchange and interest rate fluctuations, competitive product offerings, local changes in health care financing and payment systems and health care delivery systems, local product preferences and requirements, including preferences for local manufacturers; workforce instability, less intellectual property protection in certain countries than exists in the U.S. and, in certain foreign countries, longer accounts receivable cycles. Such risks and uncertainties may adversely impact our ability to implement our growth strategy in these markets and, as a result, our sales growth, market share and operating profits from our international operations may be adversely affected.

Our international operations are subject to established and developing legal and regulatory requirements for medical devices in each country in which our products are marketed and sold. Most foreign countries have medical device regulations. Further, most countries outside of the U.S. require product approvals be renewed or recertified on a regular basis in order to continue to be marketed and sold there. In addition, several countries that previously did not have regulatory requirements for medical devices have established such requirements in recent years and other countries have expanded, or plan to expand, on existing regulations, including requiring local clinical data in addition to global clinical data. These factors have caused or may cause us to experience more uncertainty, risk, expense and delay in commercializing products in certain foreign jurisdictions, which could affect our ability to obtain approvals for our products in those jurisdictions and adversely impact our net sales, market share and operating profits from our international operations.

Further, international markets are affected by economic pressure to contain healthcare costs, which can lead to more rigorous evidence requirements and lower reimbursement rates for either our products directly or procedures in which our products are used. Governments and payers may also institute changes in health care delivery systems that may reduce funding for services or encourage greater scrutiny of health care costs. In addition, certain international markets may also be affected by foreign government efforts to reference reimbursement rates in other countries. All of these types of changes may ultimately reduce selling prices of our products and/or reduce the number of procedures in which our products are used, which may adversely impact our net sales, market share and operating profits from our international operations.

In addition, our international operations are subject to other established and developing U.S. and foreign legal and regulatory requirements, including the U.S. Foreign Corrupt Practices Act (FCPA) and/or similar laws in other countries and U.S. and foreign import and export controls and licensing requirements, trade protection and embargo measures and customs laws. Global businesses, including those in the medical device industry, are facing increasing scrutiny of, and heightened enforcement efforts with respect to, their international operations. Any alleged or actual failure to comply with legal and regulatory requirements may subject us to government scrutiny, civil and/or criminal proceedings, sanctions and other liabilities, which may have a material adverse effect on our international operations, financial condition, results of operations and/or liquidity.

In a referendum on June 23, 2016, voters approved for the United Kingdom (UK) to exit the European Union (EU). As it stands, the UK will depart the EU on March 30, 2019 but the terms of its withdrawal and the nature of its future relationship with the EU are still being decided. Future exit of the UK from the EU will have numerous consequences in all areas of the business, including, economic, regulatory, operational, and the actual impact depends on the ultimate deal reached and is very difficult to assess at this time. Changes in the industry regulations could have an effect on existing CE certificates being renewed and new certificates being issued which would impact the ability to trade; however, it is impossible to assess the full impact at this stage.

In December of 2017, EU leaders announced an agreement to begin the next phase of negotiations, with talks on a transition period after March 2019 to begin in early 2018 and discussions on the future UK-EU relationship, including trade and security, to begin in March. At this stage, the materiality to us of the Brexit risk factor remains unknown and unquantifiable.

Any significant changes in the political and economic, financial, competitive, legal and regulatory or reimbursement conditions where we conduct, or plan to expand, our international operations may have a material impact on our business, financial condition or results of operations.

If we are unable to manage our debt levels, maintain investment grade credit ratings at the three ratings agencies, or experience a disruption in our cash flows it could have an adverse effect on our cost of borrowing, financial condition or results of operations.

As part of our strategy to maximize stockholder value, we use financial leverage to reduce our cost of capital. Our outstanding debt balance was $7.056 billion as of December 31, 2018 and $5.616 billion as of December 31, 2017. Although we currently have investment grade ratings at Moody's Investor Service, Standard & Poor's Rating Service and Fitch Ratings, our inability to maintain investment grade credit ratings could increase our cost of borrowing funds in the future and reduce our access to liquidity. Delays in our product development and new product launches could result in disruption in our cash flow or our ability to continue to effectively manage our debt levels could have an adverse effect on our cost of borrowing, financial condition or results of operations. In addition, our credit and security facilities contain covenants that require us to maintain specified financial ratios and place other limits on our business. If we are unable to satisfy these covenants, we may be required to obtain waivers from our lenders and no assurance can be made that our lenders would grant such waivers on favorable terms or at all and we could be required to repay any borrowings on demand.

We may record future intangible asset impairment charges related to one or more of our global reporting units, which could materially adversely impact our results of operations.

We test our goodwill balances during the second quarter of each year for impairment, or more frequently if indicators are present or changes in circumstances suggest that impairment may exist. We assess goodwill for impairment at the reporting unit level and, in evaluating the potential for impairment of goodwill, we make assumptions regarding estimated revenue projections, growth rates, cash flows and discount rates. In the second quarter of 2018, we performed our annual goodwill impairment test for all of our reporting units. In conjunction with our annual test, the fair value of each reporting unit exceeded its carrying value and none of our reporting units were at risk of impairment. Refer to *Critical Accounting Policies and Estimates* contained in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report for a discussion of key assumptions used in our testing.

On a quarterly basis, we monitor the key drivers of fair value to detect events or other changes that would warrant an interim impairment test of our goodwill and other intangible assets. Relatively small declines in the future performance and cash flows of a reporting unit or asset group, changes in our reporting units or in the structure of our business as a result of future reorganizations, acquisitions or divestitures of assets or businesses, or small changes in other key assumptions, may result in the recognition of significant asset impairment charges, which could have a material adverse impact on our results of operations.

Failure to integrate acquired businesses into our operations successfully could adversely affect our business, financial condition and operating results.

As part of our strategy to realign our business portfolio, we have completed multiple acquisitions over the past three years and may pursue additional acquisitions in the future. Our integration of acquired businesses requires significant efforts, including corporate restructuring and the coordination of information technologies, research and development, sales and marketing, operations, regulatory, supply chain, manufacturing, quality systems and finance. These efforts result in additional expenses and involve significant management time. Some of the factors that could affect the success of our acquisitions include, among others, the effectiveness of our due diligence process, our ability to execute our business

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

plan for the acquired companies, the strength of the acquired technology, results of clinical trials, regulatory approvals and reimbursement levels of the acquired products and related procedures, the continued performance of critical transition services, our ability to adequately fund acquired in-process

research and development projects and retain key employees and our ability to achieve synergies with our acquired companies, such as increasing sales of our products, achieving cost savings and effectively combining technologies to develop new products. In addition, foreign acquisitions involve unique risks, including those related to integration of operations across different geographies, cultures and languages, currency risks and risks associated with the economic, political, legal and regulatory environment in specific countries. Our failure to manage successfully and coordinate the growth of the acquired companies could have an adverse impact on our business and our future growth. In addition, we cannot be certain that the businesses we acquire will become profitable or remain so, and if our acquisitions are not successful, we may record related asset impairment charges in the future or experience other negative consequences on our results.

We may not be successful in our strategy relating to future strategic acquisitions of, investments in, or alliances with, other companies and businesses, which have been a significant source of historical growth for us, and will be key to our diversification into new markets and technologies.

Our strategic acquisitions, investments and alliances are intended to further expand our ability to offer customers effective, high quality medical devices that satisfy their interventional needs. These acquisitions, investments and alliances have been a significant source of our growth. If we are unsuccessful in our acquisitions, investments and alliances, we may be unable to grow our business. The success of our strategy relating to future acquisitions, investments or alliances will depend on a number of factors, including:

- our ability to identify suitable opportunities for acquisition, investment or alliance, if at all,
- our ability to manage acquisition, investment or alliance opportunities within our capital capacity and prioritize those investments to execute on our strategy,
- our ability to manage our due diligence process to uncover potential issues with targets,
- our ability to finance any future acquisition, investment or alliance on terms acceptable to us, if at all,
- our ability to complete acquisitions, investments or alliances in a timely manner on terms that are satisfactory to us, if at all,
- our ability to successfully integrate and operate acquired businesses,
- our ability to successfully identify and retain key target employees,
- our ability to comply with applicable laws and regulations, including foreign laws and regulations and
- our ability to protect intellectual property and to prevail in litigation related to newly acquired technologies.

Any potential future acquisitions we consummate may be dilutive to our earnings and may require additional debt or equity financing, depending on their size or nature.

We may not realize the expected benefits from our restructuring and optimization initiatives, our long-term expense reduction programs may result in an increase in short-term expenses and our efforts may lead to unintended consequences.

We monitor the dynamics of the economy, the healthcare industry and the markets in which we compete and assess opportunities for improved operational effectiveness and efficiency and to better align expenses with revenues, while preserving our ability to make investments in research and development projects, capital and our people that we believe are important to our long-term success. As a result of these assessments, we have undertaken restructuring and optimization initiatives in order to enhance our growth potential and position us for long-term success. For example, in November 2018, we announced a restructuring initiative (the 2019 Restructuring Plan) intended to support our effort to improve operating performance and meet anticipated market demands by ensuring that we are appropriately structured and resourced to deliver sustainable value to patients and customers. Key activities under the 2019 Restructuring Plan include supply chain network optimization intended to maximize our global manufacturing and distribution network capacity and building functional capabilities that support business growth. These activities are expected to be initiated in 2019, with the majority of activity expected to be complete by the end of 2021. The 2019 Restructuring Plan is expected to result in total pre-tax charges of approximately $200 million to $300 million and reduce gross annual pre-tax operating expenses by approximately $100 million to $150 million by the end of 2022 as program benefits are realized. We expect a substantial portion of the savings to be reinvested in strategic growth initiatives. These measures could yield unintended consequences, such as distraction of our management and employees, business disruption, inability to attract or retain key personnel and reduced employee productivity, which could negatively affect our business, sales, financial condition and results of operations. Moreover, our restructuring and optimization initiatives result in charges and expenses some of which impact our operating results. We cannot guarantee that the activities under our restructuring plans or other optimization initiatives will result in the desired efficiencies and estimated cost savings.

Current domestic and international economic conditions could adversely affect our cash flows and results of operations.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Uncertainty about global economic conditions, including those resulting from credit and sovereign debt issues, has caused and may continue to cause disruption in the financial markets, including diminished liquidity and credit availability. These conditions

may adversely affect our suppliers, leading them to experience financial difficulties or be unable to borrow money to fund their operations, which could cause disruptions in our ability to produce our products. Our customers may experience financial difficulties or be unable to borrow money to fund their operations, which may adversely impact their ability or decision to purchase our products, particularly capital equipment, or to pay for our products they purchase on a timely basis, if at all. In addition, we have accounts receivable factoring programs in certain European countries. Continued deterioration of the global economy or increase in sovereign debt issues may impact our ability to transfer receivables to third parties in certain of those countries in the future. Third parties such as banks offering factoring programs in these countries are looking to reduce their exposure levels to government owned or supported debt. This could result in terminations of, or changes to the costs or credit limits of our existing factoring programs. Such terminations or changes could have a negative impact on our cash flow and days sales outstanding.

The strength and timing of economic recovery remains uncertain and there can be no assurance that there will not be further deterioration in the global economy. Accordingly, we cannot predict to what extent global economic conditions, including sovereign debt issues and increased focus on healthcare systems and costs in the U.S. and abroad, may continue to impact negatively our average selling prices, net sales and profit margins, procedural volumes and reimbursement rates from third party payers. In addition, conditions in the financial markets and other factors beyond our control may adversely affect our ability to borrow money in the credit markets, access the capital markets and to obtain financing for acquisitions or other general corporate and commercial purposes.

Healthcare policy changes, including healthcare reform legislation, may have a material adverse effect on our business, financial condition, results of operations and cash flows.

Political, economic and policy influences are leading the healthcare industry to make substantial structural and financial changes that will continue affecting our results of operations. Government and private sector initiatives limiting the growth of healthcare costs (including price regulation), coverage and payment policies, comparative effectiveness of therapies, technology assessments and healthcare delivery structure reforms, are continuing in many countries where we do business. We believe that these changes are causing the marketplace to put increased emphasis on the delivery of more treatments that can reduce costs, improve efficiencies and/or increase patient access. Although we believe our less-invasive products and technologies generate favorable clinical outcomes, value and cost efficiency, the resources necessary and evidence necessary to demonstrate value to our customers, patients, payers and other stakeholders may be significant and it may take a longer period of time to gain widespread adoption. Moreover, there can be no assurance that our strategies will succeed for every product.

The Patient Protection and Affordable Care Act (ACA) and Health Care and Education Affordability Reconciliation Act of 2010 were enacted into law in the U.S. in March 2010. As a U.S. headquartered company with significant domestic sales, the medical device tax included in this law has materially affected us. The law imposed on medical device manufacturers a 2.3 percent excise tax on U.S. sales of Class I, II and III medical devices beginning in January 2013. Under the current administration, there may be a permanent repeal or an alteration of some or all elements of the ACA, but at this time it is not definite that a change will be enacted or what new healthcare provisions may be implemented. While the implementation of the medical device tax has been suspended until December 31, 2019, the status of the tax for sales after December 31, 2019 is not clear. The tax may continue to be suspended or may be reinstated at the same or at a different level effective January 1, 2020. Other provisions of this law, including comparative effectiveness research, pilot programs to evaluate alternative payment methodologies and other changes to the payment systems, have started changing the way healthcare is delivered, reimbursed and funded. While the extent to which it has affected our business is not clear, these changes, over the long-term, may adversely affect our business and results of operations.

We cannot predict the specific healthcare programs and regulations that will be ultimately implemented by regional and national governments globally. However, any changes that lower reimbursements for either our products and/or procedures using our products reduce medical procedure volumes and/or increase cost containment pressures on us or others in the healthcare sector could adversely affect our business and results of operations.

We are subject to extensive and dynamic medical device regulation, which may impede or hinder the approval or sale of our products and, in some cases, may ultimately result in an inability to obtain approval of certain products or may result in the recall or seizure of previously approved products.

Our products, marketing, sales and development activities and manufacturing processes are subject to extensive and rigorous regulation by the FDA pursuant to the Federal Food, Drug and Cosmetic Act (FDC Act), by comparable agencies in foreign countries and by other regulatory agencies and governing bodies. Under the FDC Act, medical devices must receive FDA clearance or approval or an exemption from such clearance or approval before they can be commercially marketed in the U.S. In the EU, we are required to comply

with applicable medical device directives (including the Medical Devices Directive and the Active Implantable Medical Devices Directive and beginning in May 2020, the European Medical Device Regulation) and obtain CE

Mark certification in order to market medical devices. The CE Mark is applied following approval from an independent notified body or declaration of conformity. The process of obtaining marketing approval or clearance from the FDA or by comparable agencies in foreign countries for new products, or with respect to enhancements or modifications to existing products, could:

- take a significant period of time,
- require the expenditure of substantial resources,
- involve rigorous pre-clinical and clinical testing, as well as increased post-market surveillance,
- require changes to products and
- result in limitations on the indicated uses of products.

In addition, exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. due to differing regulatory requirements; however, other countries, such as China for example, require approval in the country of origin or legal manufacturer first. Most countries outside of the U.S. require that product approvals be renewed or recertified on a regular basis, generally every four to five years. The renewal or recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where renewal or recertification applications are required, they may need to be renewed and/or approved in order to continue selling our products in those countries. There can be no assurance that we will receive the required approvals for new products or modifications to existing products on a timely basis or that any approval will not be subsequently withdrawn or conditioned upon extensive post-market study requirements.

Our global regulatory environment is becoming increasingly stringent and unpredictable, which could increase the time, cost and complexity of obtaining regulatory approvals for our products, as well as the clinical and regulatory costs of supporting those approvals. Several countries that did not have regulatory requirements for medical devices have established such requirements in recent years and other countries have expanded on existing regulations. Certain regulators are exhibiting less flexibility and are requiring local preclinical and clinical data in addition to global data. While harmonization of global regulations has been pursued, requirements continue to differ significantly among countries. We expect this global regulatory environment will continue to evolve, which could impact our ability to obtain future approvals for our products or could increase the cost and time to obtain such approvals in the future.

The European Union regulatory bodies finalized a new Medical Device Regulation (MDR) in 2017, which replaced the existing Directives and provided three years for transition and compliance. The MDR will change several aspects of the existing regulatory framework, such as updating clinical data requirements and introducing new ones, such as Unique Device Identification (UDI). We and the Notified Bodies who will oversee compliance to the new MDR face uncertainties as the MDR is rolled out and enforced by the Commission and EEA Competent Authorities, creating risks in several areas, including the CE Marking process and data transparency, in the upcoming years.

The FDA and other worldwide regulatory agencies actively monitor compliance with local laws and regulations through review and inspection of design and manufacturing practices, recordkeeping, reporting of adverse events, labeling and promotional practices. The FDA can ban certain medical devices, detain or seize adulterated or misbranded medical devices, order repair, replacement or refund of these devices and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA can take action against a company that promotes "off-label" uses. The FDA may also enjoin and restrain a company for certain violations of the FDC Act and other amending Acts pertaining to medical devices, or initiate action for criminal prosecution of such violations. Any adverse regulatory action, depending on its magnitude, may restrict a company from effectively marketing and selling its products, may limit a company's ability to obtain future premarket clearances or approvals and could result in a substantial modification to our business practices and operations. International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or that are banned or deviate from lawful performance standards, are subject to FDA export requirements.

Regulations regarding the development, manufacture and sale of medical devices are evolving and subject to future change. We cannot predict what impact, if any, those changes might have on our business. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations. Later discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory clearances or approvals, seizures or recalls of products, physician advisories or other field actions, operating restrictions and/or criminal prosecution. We may also initiate field actions as a result of a failure to strictly comply

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

with our internal quality policies. The failure to receive product approval clearance on a timely basis, suspensions of regulatory clearances, seizures or recalls of products, physician advisories or other field actions, or the withdrawal of product approval by the FDA or by comparable agencies in foreign countries could have a material adverse effect on our business, financial condition or results of operations.

Our products are continually subject to clinical trials conducted by us, our competitors or other third parties, the results of which may be unexpected, or perceived as unfavorable by the market, and could have a material adverse effect on our business, financial condition or results of operations.

As a part of the regulatory process of obtaining marketing clearance for new products and new indications for existing products, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints. Unexpected or inconsistent clinical data from existing or future clinical trials conducted by us, by our competitors or by third parties, including acquired businesses prior to acquisition by us, or the FDA's or the market's perception of this clinical data, may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate and our business, financial condition, results of operations or future prospects.

Our future growth is dependent upon the development of new products and enhancement of existing products, which requires significant research and development, clinical trials and regulatory approvals, all of which may be very expensive and time-consuming and may not result in commercially viable products.

In order to develop new products and enhance existing products, we focus our research and development programs largely on the development of next-generation and novel technology offerings across multiple programs and businesses. The development of new products and enhancement of existing products requires significant investment in research and development, clinical trials and regulatory approvals. The results of our product development efforts may be affected by a number of factors, including our ability to anticipate customer needs, innovate and develop new products, complete clinical trials, obtain regulatory approvals and reimbursement in the United States and abroad, manufacture products in a cost-effective manner, obtain appropriate intellectual property protection for our products and gain and maintain market approval of our products. There can be no assurance that any products now in development or that we may seek to develop in the future will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch new products and enhanced products, our ability to maintain or expand our market position in the markets in which we participate may be materially adversely impacted. Further, we are continuing to investigate and have completed several acquisitions that involve opportunities to further expand our presence in and diversify into, priority growth areas by accessing new products and technologies. There can be no assurance that our investments will be successful or that we will be able to access new products and technologies on terms favorable to us, or that these products and technologies will achieve commercial feasibility, obtain regulatory approval or gain market acceptance. A delay in the development or approval of new products and technologies or our decision to reduce our investments may adversely impact the contribution of these technologies to our future growth.

Additionally, certain products or groups of products, in particular new products or enhancements of existing products, may have a disproportionate impact on our business, financial condition and results of operations. Failure to meet growth projections, poor clinical outcomes, increasing regulatory requirements, launch delays and inability to effectively scale manufacturing and achieve targeted margins with respect to any of these products or groups of products in particular may materially adversely impact on our business, financial condition and results of operations.

The medical device industry and its customers continue to face scrutiny and regulation by governmental authorities and are often the subject of numerous investigations, often involving marketing and other business practices or product quality issues including device recalls or advisories. These investigations could result in the commencement of civil and criminal proceedings; imposition of substantial fines, penalties and administrative remedies, including corporate integrity agreements, stipulated judgments or exclusion; diversion of our employees and management's attention; imposition of administrative costs and have an adverse effect on our financial condition, results of operations and liquidity; and may lead to greater governmental regulation in the future.

The medical devices we design, develop, manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. These authorities continue to highly scrutinize our industry. We have received and in the future may receive, subpoenas and other requests for information from Congress and other state and federal governmental agencies, including, among others, the U.S. Department of Justice (DOJ), the Office of Inspector General of the Department of Health and Human Services (HHS) and the Department of Defense, as well as from foreign governments and agencies. The requests and/or subpoenas we have received relate primarily to financial arrangements with healthcare providers, regulatory compliance and sale and/or product promotional practices. We have cooperated with these subpoenas and other requests for information and expect to continue to do so in the future. We cannot predict when a matter will be resolved, the outcome of the matter or its impact on us and cooperation may involve significant costs, including document production costs. An adverse outcome in any matter could include the commencement of an investigation, civil and criminal proceedings, substantial fines, penalties and administrative remedies, including exclusion from government reimbursement programs, entry into Corporate Integrity Agreements (CIAs) with governmental agencies and amendments to any existing CIAs. In addition, resolution of any matter could involve the imposition of additional and costly compliance obligations. Cooperation with requests and investigations

from external agencies result in employee resource costs and diversion of employee focus. If any requests or investigations continue over a long period of time, they could divert the attention of management from the day-to-day operations of our business and impose significant additional administrative burdens on us. These potential consequences, as well as any adverse outcome from these requests or investigations, could have a material adverse effect on our financial condition, results of operations and liquidity.

In addition, certain foreign governments, state governments (including that of Massachusetts, where we are headquartered) and the U.S. federal government have enacted legislation aimed at increasing transparency of our interactions with healthcare providers. As an example, compliance with the U.S. Physician Payment Sunshine Act requires us by law to disclose payments and other transfers of value to all U.S. physicians and U.S. teaching hospitals at the U.S. federal level made after August 1, 2013. Any failure to comply with these legal and regulatory requirements could impact our business. In addition, we have and may continue to devote substantial additional time and financial resources to further develop and implement enhanced structure, policies, systems and processes to comply with enhanced legal and regulatory requirements, which may also impact our business.

We anticipate that governmental authorities will continue to scrutinize our industry closely and that additional regulation may increase compliance and legal cost and exposure to litigation and have additional adverse effects on our operations.

Changes in tax laws, unfavorable resolution of tax contingencies, or exposure to additional income tax liabilities could have a material impact on our financial condition, results of operations and/or liquidity.

We are subject to income taxes as well as non-income based taxes, in both the U.S. and various foreign jurisdictions. We are subject to ongoing tax audits in various jurisdictions. Tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly assess the likely outcomes of these audits to determine the appropriateness of our tax provision, and we have established contingency reserves for material, known tax exposures. However, the calculation of such tax exposures involves the application of complex tax laws and regulations in many jurisdictions, as well as interpretations as to the legality under European Union state aid rules of tax advantages granted in certain jurisdictions. Therefore, there can be no assurance that we will accurately predict the outcomes of these disputes or other tax audits or that issues raised by tax authorities will be resolved at a financial cost that does not exceed our related reserves and the actual outcomes of these disputes and other tax audits could have a material impact on our results of operations or financial condition.

Changes in tax laws and regulations, or their interpretation and application, in the jurisdictions where we are subject to tax could materially impact our effective tax rate. The U.S. enacted the Tax Cuts and Jobs Act (TCJA) on December 22, 2017 and we expect the U.S. Treasury to issue future notices and regulations under the TCJA. Certain provisions of the TCJA and the regulations issued thereunder could have a significant impact on our future results of operations as could interpretations made by the Company in the absence of regulatory guidance and judicial interpretations.

Additionally, the Organization for Economic Co-operation and Development (OECD), the European Commission (EC) and individual taxing jurisdictions where we and our affiliates do business have recently focused on issues related to the taxation of multinational corporations. The OECD has released its comprehensive plan to create an agreed set of international rules for fighting base erosion and profit shifting. In addition, the OECD, the EC and individual counties are examining changes to how taxing rights should be allocated among countries considering the digital economy. As a result, the tax laws in the U.S. and other countries in which we and our affiliates do business could change on a prospective or retroactive basis and any such changes could materially adversely affect our business.

Our operations in Puerto Rico and Costa Rica presently benefit from various tax incentives and grants. Unless these incentives and grants are extended, they will expire between 2023 and 2028. If we are unable to renew, extend, or obtain new incentive and grants, the expiration of the existing incentives and grants could have a material impact on our financial results in future periods.

We may not effectively be able to protect our intellectual property or other sensitive data, which could have a material adverse effect on our business, financial condition or results of operations.

The medical device market in which we primarily participate is largely technology driven. Physician customers have historically moved quickly to new products and new technologies. As a result, intellectual property rights, particularly patents and trade secrets, play a significant role in product development and differentiation. However, intellectual

property litigation is inherently complex and unpredictable and appellate courts can overturn lower court decisions. Furthermore, as our business increasingly relies on technology systems and infrastructure, our intellectual property, other proprietary technology and other sensitive data are potentially vulnerable to loss, damage or misappropriation. Finally, our ability to protect novel business models is uncertain.

Competing parties in our industry frequently file multiple suits to leverage patent portfolios across product lines, technologies and geographies and to balance risk and exposure between the parties. In some cases, several competitors are parties in the same

proceeding, or in a series of related proceedings, or litigate multiple features of a single class of devices. These forces frequently drive settlement not only of individual cases, but also of a series of pending and potentially related and unrelated cases. In addition, although monetary and injunctive relief is typically sought, remedies and restitution are generally not determined until the conclusion of the trial court proceedings and can be modified on appeal. Accordingly, the outcomes of individual cases are difficult to time, predict or quantify and are often dependent upon the outcomes of other cases in other geographies.

A number of third parties have asserted that our current and former product offerings infringe patents owned or licensed by them. We have similarly asserted that products sold by our competitors infringe patents owned or licensed by us. Adverse outcomes in one or more of the proceedings against us could limit our ability to sell certain products in certain jurisdictions, or reduce our operating margin on the sale of these products and could have a material adverse effect on our financial condition, results of operations or liquidity.

Patents and other proprietary rights are and will continue to be essential to our business and our ability to compete effectively with other companies will be dependent upon the proprietary nature of our technologies. We rely upon trade secrets, know-how, continuing technological innovations, strategic alliances and licensing opportunities to develop, maintain and strengthen our competitive position. We pursue a policy of generally obtaining patent protection in both the U.S. and abroad for patentable subject matter in our proprietary devices and attempt to review third-party patents and patent applications to the extent publicly available in order to develop an effective patent strategy, avoid infringement of third-party patents, identify licensing opportunities and monitor the patent claims of others. We currently own numerous U.S. and foreign patents and have numerous patent applications pending. We also are party to various license agreements pursuant to which patent rights have been obtained or granted in consideration for cash, cross-licensing rights or royalty payments. No assurance can be made that any pending or future patent applications will result in the issuance of patents, that any current or future patents issued to, or licensed by, us will not be challenged or circumvented by our competitors, or that our patents will not be found invalid. In addition, we may have to take legal action in the future to protect our patents, trade secrets or know-how or to assert them against claimed infringement by others. Any legal action of that type could be costly and time consuming and no assurances can be made that any lawsuit will be successful. We are generally involved as both a plaintiff and a defendant in a number of patent infringement and other intellectual property-related actions. The invalidation of key patents or proprietary rights that we own, or an unsuccessful outcome in lawsuits to protect our intellectual property, could have a material adverse effect on our business, financial condition or results of operations.

In addition, the laws of certain countries in which we market and plan on manufacturing some of our products in the near future, do not protect our intellectual property rights to the same extent as the laws of the U.S. If we are unable to protect our intellectual property in these countries, it could have a material adverse effect on our business, financial condition or results of operations.

Furthermore, our intellectual property, other proprietary technology and other sensitive data are potentially vulnerable to loss, damage or misappropriation from system malfunction, computer viruses and unauthorized access to our data or misappropriation or misuse thereof by those with permitted access and other events. While we have invested to protect our intellectual property, products and other data and continue to work diligently in this area, there can be no assurance that our precautionary measures will prevent breakdowns, breaches, cyber-attacks or other events. Such events could have a material adverse effect on our reputation, business, financial condition or results of operations.

We rely on the proper function, availability and security of information technology systems to operate our business and a cyber-attack or other breach of these systems could have a material adverse effect on our business, financial condition or results of operations.

We rely on information technology systems, including technology from third party vendors, to process, transmit and store electronic information in our day-to-day operations. Similar to other large multi-national companies, the size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, the increasing need to protect patient and customer information and changing customer patterns. In addition, third parties may attempt to hack into our products to obtain data relating to patients or disrupt performance of our products or to access our proprietary information and the technology from third party vendors that we rely upon may have defects or vulnerabilities which, in turn, create vulnerabilities or disruptions in our system. Any failure by us to maintain or protect our information technology systems, products and data integrity, including from cyber-attacks, intrusions or other breaches, could result in the unauthorized access to patient data and personally identifiable information, theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations, or, in the worst case, could result in harm to patients. Such failure, or demonstration of vulnerability to such failure, may also result in additional regulatory scrutiny. We also grow our company through acquisitions and may face risks associated with defects and vulnerabilities in their systems as we work to integrate the acquisitions into our information technology system.

In the U.S., federal and state privacy and security laws require certain of our operations to protect the confidentiality of personal information including patient medical records and other health information. In Europe, the Data Protection Directive requires us to manage individually identifiable information in the EU and, the new General Data Protection Regulation may impose fines of up to four percent of our global revenue in the event of violations after implementation of the requirements on May 25, 2018. Internationally, some countries have also passed laws that require individually identifiable data on their citizens to be maintained on local servers and that may restrict transfer or processing of that data. We believe that we meet the expectations of applicable regulations and that the ongoing costs and impacts of ensuring compliance with such rules are not material to our business. However, there is no guarantee that we will avoid enforcement actions by governmental bodies. Enforcement actions could be costly and interrupt regular operations of our business. Any of these events, in turn, may cause us to lose existing customers, have difficulty preventing, detecting and controlling fraud, have disputes with customers, physicians and other healthcare professionals, be subject to legal claims and liability, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach or theft of intellectual property, or suffer other adverse consequences, any of which could have a material adverse effect on our business, financial condition or results of operations.

Pending and future intellectual property litigation could be costly and disruptive to us.

We operate in an industry that is susceptible to significant intellectual property litigation and, in recent years, it has been common for companies in the medical device field to aggressively challenge the patent rights of other companies. We are currently the subject of various patent litigation proceedings and other proceedings described in more detail under *Note J – Commitments and Contingencies* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report. Intellectual property litigation is expensive, complex and lengthy and its outcome is difficult to predict. Adverse outcomes in one or more of these matters could have a material adverse effect on our ability to sell certain products and on our operating margins, financial condition, results of operation or liquidity. Pending or future patent litigation may result in significant royalty or other payments or injunctions that can prevent the sale of products and may significantly divert the attention of our technical and management personnel. In the event that our right to market any of our products is successfully challenged, we may be required to obtain a license on terms which may not be favorable to us, if at all. If we fail to obtain a required license or are unable to design around a patent, our business, financial condition or results of operations could be materially adversely affected.

Pending and future product liability claims and other litigation, including private securities litigation, stockholder derivative suits and contract litigation, may adversely affect our financial condition and results of operations or liquidity.

The design, manufacturing and marketing of medical devices of the types that we produce entail an inherent risk of product liability claims. Many of the medical devices that we manufacture and sell are designed to be implanted in the human body for long periods of time or indefinitely. A number of factors could result in an unsafe condition or injury to, or death of, a patient with respect to these or other products that we manufacture or sell, including physician technique and experience in performing the surgical procedure, component failures, manufacturing flaws, design defects, off-label use or inadequate disclosure of product-related risks or product-related information. These factors could result in product liability claims, a recall of one or more of our products or a safety alert relating to one or more of our products. Product liability claims may be brought by individuals or by groups seeking to represent a class.

We are currently the subject of product liability litigation proceedings and other proceedings described in more detail under *Note J – Commitments and Contingencies* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report. The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, including not only actual damages, but also punitive damages. The magnitude of the potential losses relating to these lawsuits may remain unknown for substantial periods of time. In addition, the cost to defend against any future litigation may be significant. Product liability claims, securities and commercial litigation and other litigation in the future, regardless of the outcome, could have a material adverse effect on our financial condition, results of operations or liquidity. Additionally, we maintain an insurance policy providing limited coverage against securities claims and we are substantially self-insured with respect to product liability claims and fully self-insured with respect to intellectual property infringement claims. The fact that we do not maintain third-party insurance coverage for all categories of losses increases our exposure to unanticipated claims and adverse decisions and these losses could have a material adverse effect on our financial condition, results of operations or liquidity.

Any failure to meet regulatory quality standards applicable to our manufacturing and quality processes could have an adverse effect on our business, financial condition and results of operations.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

As a medical device manufacturer, we are required to register our establishments and list our devices with the FDA and are subject to periodic inspection by the FDA for compliance with its Quality System Regulation requirements, which require manufacturers

of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, the Federal Medical Device Reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA which may result in observations on Form 483 and in some cases warning letters that require corrective action. In the European Community, we are required to maintain certain International Standards Organization (ISO) certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. Many other countries in which we do business have requirements similar to those of the U.S. or the EU and other foreign governments or agencies may subject us to periodic inspections as well. If we, or our manufacturers, fail to adhere to quality system regulations or ISO requirements, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

Interruption of our manufacturing operations could adversely affect our results of operations and financial condition.

Our products are designed and manufactured in technology centers around the world, either by us or third parties. In most cases, the manufacturing of any specific product is concentrated in one or a few locations. Factors such as a failure to follow specific internal protocols and procedures, equipment malfunction, environmental factors or damage to one or more of our facilities could adversely affect our ability to manufacture our products. In the event of an interruption in manufacturing, we may be unable to quickly move to alternate means of producing affected products or to meet customer demand. In the event of a significant interruption, for example, as a result of a failure to follow regulatory protocols and procedures, we may experience lengthy delays in resuming production of affected products due primarily to needs for regulatory approvals. As a result, we may experience loss of market share, which we may be unable to recapture and harm to our reputation, which could adversely affect our results of operations and financial condition.

Disruptions in the supply of the materials and components used in manufacturing our products or the sterilization of our products by third-party vendors could adversely affect our results of operations and financial condition.

We purchase many of the materials and components used in manufacturing our products from third-party vendors. Certain of these materials and components are purchased from single sources due to quality considerations, expertise, costs or constraints resulting from regulatory requirements. In certain cases we may not be able to establish additional or replacement vendors for such materials or components in a timely or cost effective manner, largely as a result of FDA regulations that require validation of materials and components prior to their use in our products and the complex nature of our and many of our vendors' manufacturing processes. A reduction or interruption in the supply of materials and components used in manufacturing our products, an inability to timely develop and validate alternative sources if required or a significant increase in the price of such materials or components could adversely affect our results of operations and financial condition.

In addition, many of our products require sterilization prior to sale and we utilize a mix of internal resources and contract sterilizers to perform this service. To the extent we or our contract sterilizers are unable to sterilize our products, whether due to capacity, availability of materials for sterilization, regulatory or other constraints, we may be unable to transition to other contract sterilizer, sterilizer locations or sterilization methods in a timely or cost effective manner or at all, which could have an adverse impact on our results of operations and financial condition.

One of our contract sterilizers, Sterigenics U.S. LLC (Sterigenics), uses ethylene oxide to provide sterilization services for certain men's health products within our Urology and Pelvic Health business. In October 2018, the DuPage County State's Attorney and Illinois Attorney General filed a lawsuit against Sterigenics over the emissions in connection with the use of ethylene oxide during sterilization at Sterigenics' Willowbrook, Illinois plant. On February 15, 2019, the Illinois Environmental Protection Agency (EPA) took action to suspend operations at the Willowbrook facility. Sterigenics is challenging the action by the Illinois EPA. We are committed to ethical and sustainable business practices and have an expectation that our partners comply with all applicable regulations. We believe we currently have adequate inventory levels to sustain the disruption at the Willowbrook facility for the near term and are also pursuing various options to manage any impact to patients or our financial results, including accelerating our plans to move to existing sterilization facilities in our supply chain network. If we are unable to execute any of these options, there may be a material impact to our Urology and Pelvic Health business in the first half of 2019.

Our share price has been volatile and may fluctuate, and accordingly, the value of an investment in our common stock may also fluctuate.

Stock markets in general and our common stock in particular have experienced significant price and trading volume volatility over recent years. The market price and trading volume of our common stock may continue to be subject to significant fluctuations

due to factors described under this Item 1A. Risk Factors, as well as economic and geopolitical conditions in general and to variability in the prevailing sentiment regarding our operations or business prospects, as well as, among other things, changing investment priorities of our stockholders. Because the market price of our common stock fluctuates significantly, stockholders may not be able sell their shares at attractive prices.

If we are unable to attract or retain key personnel, it could have an adverse effect on our business, financial condition and results from operations.

In our industry, there is substantial competition for key personnel in the regions in which we operate and we may face increased competition for such employees, particularly in emerging markets as the trend toward globalization continues. Our business depends to a significant extent on the continued service of senior management and other key personnel, the development of additional management personnel and the hiring of new qualified employees. There can be no assurance that we will be successful in retaining and developing existing personnel or recruiting new personnel. The loss of one or more key employees, our ability to attract or develop additional qualified employees or any delay in hiring key personnel could have material adverse effects on our business, financial condition or results of operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our world headquarters is located in Marlborough, Massachusetts, with regional headquarters located in Singapore and Voisins-le-Bretonneux, France. As of December 31, 2018, our principal manufacturing and technology centers were located in Minnesota, California and Indiana within the U.S., as well as internationally in Ireland, Costa Rica, Puerto Rico, Malaysia, Brazil and Switzerland. Our products are distributed worldwide from customer fulfillment centers in Massachusetts and the Netherlands. As of December 31, 2018, we maintained 16 principal manufacturing facilities, including seven in the U.S., three in Ireland, two in Costa Rica, one in Puerto Rico, one in Malaysia, one in Brazil and one in Switzerland, as well as various distribution and technology centers around the world. Many of these facilities produce and manufacture products for more than one of our divisions and include research facilities. The following is a summary of our facilities as of December 31, 2018 (in approximate square feet):

	Owned (1)	Leased (2)	Total
U.S.	4,043,000	1,283,000	5,326,000
International	2,269,000	1,304,000	3,573,000
	6,312,000	**2,587,000**	**8,899,000**

(1) Includes our principal manufacturing facilities in Minnesota, Ireland, Puerto Rico and one facility in Costa Rica, our manufacturing facility in Malaysia, our customer fulfillment centers in Massachusetts, the Netherlands and Japan, and our global headquarters location in Marlborough, Massachusetts.

(2) Includes our principal manufacturing facilities in California, Indiana, Brazil, Switzerland and one in Costa Rica, and our regional headquarters located in Singapore and Voisins-le-Bretonneux, France.

ITEM 3. LEGAL PROCEEDINGS

See *Note J – Commitments and Contingencies* to our consolidated financial statements included in Item 8 of this Annual Report and incorporated herein by reference.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on the New York Stock Exchange (NYSE) under the symbol "BSX."

Holders of Record

As of January 31, 2019, there were 8,087 holders of record of our common stock.

Dividends

We did not pay a cash dividend in 2018, 2017 or 2016 and currently we do not intend to pay cash dividends. We may consider declaring and paying a cash dividend in the future; however, there can be no assurance that we will do so.

Securities Authorized for Issuance under Equity Compensation Plans

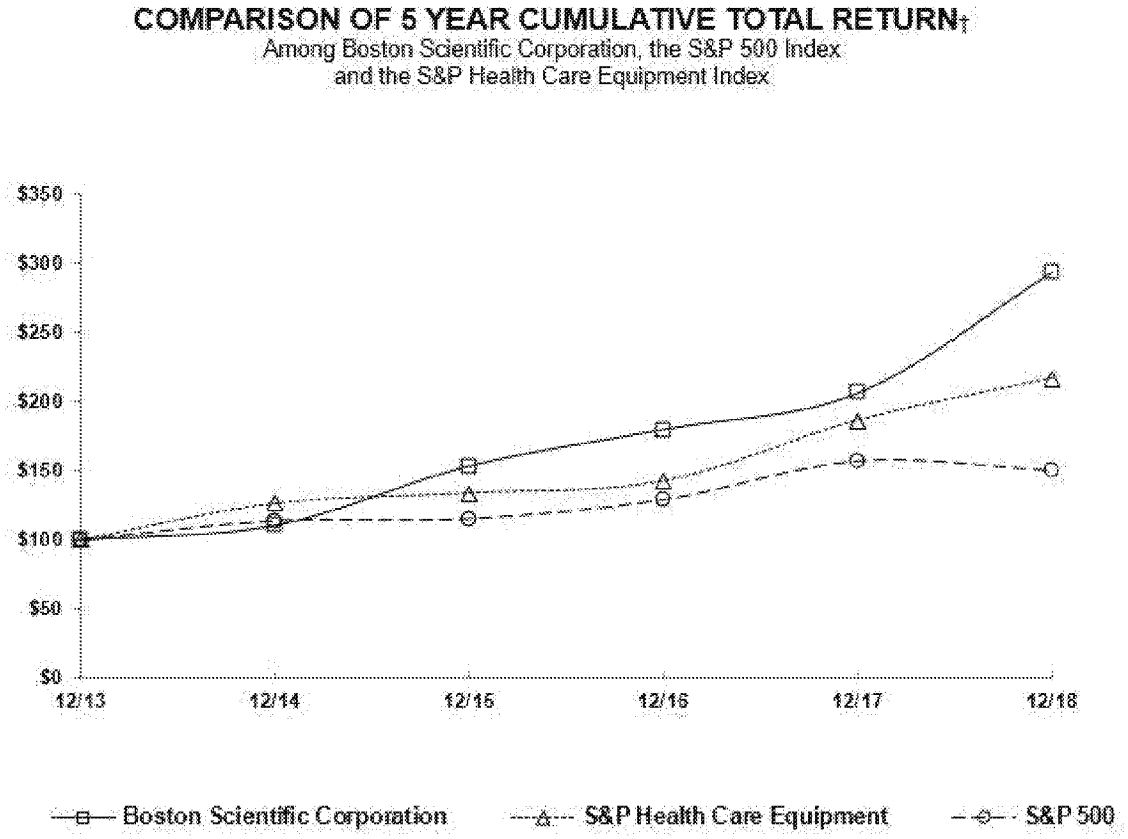
Please see Item 12. "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" under Part III of this Annual Report for information on where to find information required by Item 201(d) of Regulation S-K.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

On January 25, 2013, our Board of Directors approved and on January 29, 2013, we announced a program authorizing the repurchase of up to $1.000 billion of our common stock. In 2014, we used $125 million of cash generated from operations to repurchase approximately 10 million shares of our common stock pursuant to our share repurchase authorizations. We made no share repurchases in 2018, 2017 or 2016. Refer to *Note K - Stockholders' Equity* to our consolidated financial statements contained in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional information. As of December 31, 2018, we had approximately $535 million remaining available under the 2013 share repurchase program.

Stock Performance Graph

The graph below compares the five-year total return to stockholders on our common stock with the return of the Standard & Poor's (S&P) 500 Stock Index and the S&P Health Care Equipment Index. The graph assumes $100 was invested in our common stock and in each of the named indices on December 31, 2013 and that any dividends were reinvested.



Note: The stock price performance shown on the graph above is not indicative of future price performance. This graph shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act,

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

regardless of any general incorporation language in such filing.

ITEM 6. SELECTED FINANCIAL DATA

FIVE-YEAR SELECTED FINANCIAL DATA

(in millions, except per share data)

Operating Data

Year Ended December 31,	2018	2017	2016	2015	2014
Net sales	$ 9,823	$ 9,048	$ 8,386	$ 7,477	$ 7,380
Gross profit	7,011	6,455	5,962	5,304	5,170
Total operating expenses	5,504	5,170	5,515	5,587	5,471
Operating income (loss)	1,506	1,285	447	(283)	(301)
Income (loss) before income taxes	1,422	933	177	(650)	(509)
Net income (loss)	1,671	104	347	(239)	(119)
Net income (loss) per common share:					
Basic	$ 1.21	$ 0.08	$ 0.26	$ (0.18)	$ (0.09)
Assuming dilution	$ 1.19	$ 0.08	$ 0.25	$ (0.18)	$ (0.09)

Balance Sheet Data

As of December 31,	2018	2017	2016	2015	2014
Cash, cash equivalents and marketable securities	$ 146	$ 188	$ 196	$ 319	$ 587
Working capital (deficit)	(1,257)	(1,832)	(348)	1,041	760
Total assets	20,999	19,042	18,096	18,133	17,024
Borrowings (short-term)	2,253	1,801	64	3	403
Borrowings (long-term)	4,803	3,815	5,420	5,674	3,841
Stockholders' equity	8,726	7,012	6,733	6,320	6,457
Book value per common share ††	$ 6.30	$ 5.11	$ 4.94	$ 4.69	$ 4.86

†† Book value per common share is calculated using shares outstanding as of December 31, for each year, respectively shown.

The data above should be read in conjunction with our consolidated financial statements, including the notes thereto, included in Item 8. Financial Statements and Supplementary Data of our Annual Report on Form 10-K.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information management believes to be relevant to understanding the financial condition and results of operations of Boston Scientific Corporation and its subsidiaries. For a full understanding of our financial condition and results of operations, this discussion should be read in conjunction with our consolidated financial statements and accompanying notes included in Item 8. Financial Statements and Supplementary Data of this Annual Report.

Executive Summary

Financial Highlights and Trends

In 2018, we generated net sales of $9.823 billion, as compared to $9.048 billion in 2017. This increase of $775 million, or 8.6 percent, included operational growth of 8.0 percent and the positive impact of 60 basis points from foreign currency fluctuations. Operational net sales included approximately $78 million in 2018 due to the acquisitions of Symetis SA (Symetis) in the second quarter of 2017, NxThera, Inc. (NxThera) in the second quarter of 2018, Claret Medical, Inc. (Claret) in the third quarter of 2018 and Augmenix, Inc. (Augmenix) in the fourth quarter of 2018, each with no prior period related net sales.[1] Refer to the *Business and Market Overview* section for further discussion of our net sales by global business.

Our reported net income in 2018 was $1.671 billion, or $1.19 per diluted share. Our reported results for 2018 included certain charges and/or credits totaling $389 million (after-tax), or $0.28 per diluted share. Excluding these items, adjusted net income for 2018 was $2.060 billion, or $1.47 per diluted share.[1]

Our reported net income in 2017 was $104 million, or $0.08 per diluted share. Our reported results for 2017 included certain charges and/or credits totaling $1.647 billion (after-tax), or $1.18 per diluted share. Excluding these items, adjusted net income for 2017 was $1.752 billion, or $1.26 per diluted share.[1]

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

[1] Operational net sales growth rates, which exclude the impact of foreign currency fluctuations and adjusted net income and adjusted net income per share, which exclude certain items required by generally accepted accounting principles in the United States (U.S. GAAP), are not prepared in accordance with U.S. GAAP and should not be considered in isolation from, or as a replacement for, the most directly comparable GAAP measure. Refer to *Additional Information* for a discussion of management's use of these non-GAAP financial measures.

The following is a reconciliation of our results of operations prepared in accordance with U.S. GAAP to those adjusted results considered by management. Refer to *Results of Operations* for a discussion of each reconciling item:

	Year Ended December 31, 2018	
(in millions, except per share data)	**Net Income (Loss)**	**Impact per Share**
GAAP net income (loss)	**$ 1,671**	**$ 1.19**
Non-GAAP adjustments:		
Amortization expense	520	0.37
Intangible asset impairment charges	31	0.02
Acquisition-related net charges (credits)	5	0.00
Restructuring and restructuring-related net charges (credits)	77	0.05
Litigation-related net charges (credits)	79	0.06
Investment impairment charges	6	0.00
Discrete tax items	(328)	(0.23)
Adjusted net income	**$ 2,060**	**$ 1.47**

	Year Ended December 31, 2017	
(in millions, except per share data)	**Net Income (Loss)**	**Impact per Share**
GAAP net income (loss)	**$ 104**	**$ 0.08**
Non-GAAP adjustments:		
Amortization expense	492	0.35
Intangible asset impairment charges	4	0.00
Acquisition-related net charges (credits)	9	0.01
Restructuring and restructuring-related net charges (credits)	75	0.05
Litigation-related net charges (credits)	172	0.12
Investment impairment charges	36	0.03
Discrete tax items	861	0.62
Adjusted net income	**$ 1,752**	**$ 1.26**

Cash provided by operating activities was $310 million in 2018. As of December 31, 2018, we had total debt of $7.056 billion, *Cash and cash equivalents* of $146 million and a working capital deficit of $1.257 billion. Refer to *Liquidity and Capital Resources* for further information.

Business and Market Overview

The following section describes an overview of our product offerings and results of operations by business unit. For additional information on our businesses and their product offerings, see Item 1. Business of this Annual Report.

Effective January 1, 2018, following organizational changes to align the structure of our business with our focus on active implantable devices, we revised our reportable segments, in accordance with FASB ASC Topic 280, *Segment Reporting*. The revision reflects a reclassification of our Neuromodulation business from our MedSurg segment to our newly created Rhythm and Neuro segment. We have revised prior year amounts to conform to the current year's presentation (as denoted with an asterisk (*) throughout). There was no revision to operating segments or reporting units as a result of the organizational change. Refer to *Note A – Significant Accounting Policies* to our consolidated financial statements in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional information.

MedSurg

Endoscopy

Our Endoscopy business develops and manufactures devices to diagnose and treat a broad range of gastrointestinal (GI) and pulmonary conditions with innovative, less invasive technologies.

Our net sales of Endoscopy products of $1.762 billion represented approximately 18 percent of our consolidated net sales in 2018. Our Endoscopy net sales increased $143 million, or 8.8 percent, in 2018, as compared to 2017. This increase included operational net sales growth of 8.3 percent and the positive impact of 50 basis points from foreign currency fluctuations, as compared to 2017. This year-over-year increase was primarily driven by growth in our hemostasis franchise featuring our Resolution 360™ Clip, our biliary franchise with both our SpyGlass™ DS Direct Visualization System and AXIOS™ Stent and Electrocautery Enhanced Delivery System and our infection prevention products and pathology services.

Urology and Pelvic Health

Our Urology and Pelvic Health business develops and manufactures devices to treat various urological and pelvic conditions for both male and female anatomies.

Our net sales of Urology and Pelvic Health products of $1.245 billion represented approximately 13 percent of our consolidated net sales in 2018. Urology and Pelvic Health net sales increased $122 million, or 10.8 percent, in 2018, as compared to 2017. This increase included operational net sales growth of 10.6 percent and the positive impact of 20 basis points from foreign currency fluctuations, as compared to 2017. This year-over-year increase was primarily attributable to growth in sales of our stone franchise, including our LithoVue™ Digital Flexible Ureteroscope, our men's health products and our benign prostatic hyperplasia (BPH) product family, including the Rezūm™ System purchased as part of our NxThera acquisition and the SpaceOAR™ Hydrogel System purchased as part of our Augmenix acquisition.

Rhythm and Neuro

Cardiac Rhythm Management

Our Cardiac Rhythm Management (CRM) business develops and manufactures a variety of implantable devices that monitor the heart and deliver electricity to treat cardiac abnormalities.

Our net sales of CRM products of $1.951 billion represented approximately 20 percent of our consolidated net sales in 2018. Our net sales of CRM products increased $56 million, or 2.9 percent, in 2018, as compared to 2017. This increase included operational net sales growth of 2.1 percent and the positive impact of 80 basis points from foreign currency fluctuations, as compared to 2017. This year-over-year increase was driven by the global strength of our implantable cardioverter defibrillator (ICD), our implantable cardiac resynchronization therapy defibrillator (CRT-D) and our subcutaneous implantable cardiac defibrillator (S-ICD) products. Our current generation of ICD and CRT-D products were

both favorably impacted by our U.S. magnetic resonance imaging (MRI) safe conditional labeling, which was approved by the FDA in September 2017 and launched in the fourth quarter of 2017. Our defibrillator growth was also driven by a combination of the ongoing global commercialization of our RESONATE™ family of ICD and CRT-D devices which includes our HeartLogic™ Heart Failure (HF) Diagnostic and the increasing market penetration of our S-ICDs. This year-over-year defibrillator growth was partially offset by declines in our pacemaker portfolio due to market share loss as a result of competitive product entrance.

Electrophysiology

Our Electrophysiology business develops and manufactures less-invasive medical technologies used in the diagnosis and treatment of rate and rhythm disorders of the heart.

Our net sales of Electrophysiology products of $311 million represented approximately three percent of our consolidated net sales in 2018. Our Electrophysiology net sales increased $33 million, or 12.1 percent, in 2018, as compared to 2017. This increase included operational net sales growth of 10.9 percent and the positive impact of 120 basis points from foreign currency fluctuations, as compared to 2017. This year-over-year increase was primarily driven by global expansion of our Rhythmia™ Mapping System products and capital equipment offerings, our expanded portfolio of navigation enabled open-irrigated catheters, including the Blazer IntellaNav MiFi™ Open-Irrigated catheter, and advanced diagnostic catheters, including the IntellaMap Orion™ Mapping Catheter.

Neuromodulation

Our Neuromodulation business develops and manufactures devices to treat various neurological movement disorders and manage chronic pain.

Our net sales of Neuromodulation products of $779 million represented eight percent of our consolidated net sales in 2018. Neuromodulation net sales increased $144 million, or 22.7 percent, in 2018, as compared to 2017. This increase included operational net sales growth of 22.5 percent and the positive impact of 20 basis points from foreign currency fluctuations, as compared to 2017. This year-over-year increase was primarily driven by the successful launch of Spectra WaveWriter™ Spinal Cord Stimulator (SCS) Systems in the U.S. and the continued strong sales growth in our Vercise™ Deep Brain Stimulation (DBS) Systems.

Cardiovascular

Interventional Cardiology

Our Interventional Cardiology business develops and manufactures technologies for diagnosing and treating coronary artery disease and other cardiovascular disorders including structural heart conditions.

Our net sales of Interventional Cardiology products of $2.590 billion represented approximately 26 percent of our consolidated net sales in 2018. Our Interventional Cardiology net sales increased $171 million, or 7.1 percent, in 2018, as compared to 2017. This increase included operational net sales growth of 6.6 percent and the positive impact of 50 basis points from foreign currency fluctuations, as compared to 2017. This year-over-year increase was primarily related to our structural heart therapies, including sales of our WATCHMAN™ Left Atrial Appendage Closure (LAAC) Device, our ACURATE™ Transcatheter Aortic Valve Replacement (TAVR) platform purchased as part of our Symetis acquisition, our Sentinel™ Cerebral Embolic Protection System purchased as part of our Claret acquisition and our complex percutaneous coronary interventions (PCI) product offerings, partially offset by a decline in sales of our drug-eluting coronary stent product offerings.

Peripheral Interventions

Our Peripheral Interventions business develops and manufactures products to diagnose and treat peripheral arterial diseases, including a broad line of medical devices used in percutaneous transluminal angioplasty (PTA) and peripheral vascular diseases, as well as products to diagnose, treat and ease various forms of cancer.

Our net sales of Peripheral Interventions products of $1.187 billion represented approximately 12 percent of our consolidated net sales in 2018. Our Peripheral Interventions net sales increased $106 million, or 9.8 percent, in 2018, as compared to 2017. This increase included operational net sales growth of 9.2 percent and the positive impact of 60 basis points from foreign currency fluctuations, as compared to 2017. This year-over-year increase was primarily driven by strong performance in each region, particularly in Asia Pacific and U.S., and growth in our interventional oncology product solutions, drug-eluting technologies, including Ranger™ Drug-Coated Balloon and Eluvia™ Drug Eluting Vascular Stent System and core technologies to treat vascular diseases.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Emerging Markets

As part of our strategic imperatives to drive global expansion, described in *Item 1. Business* of this Annual Report, we are seeking to grow net sales and market share by expanding our global presence, including in Emerging Markets. We define Emerging Markets as including 20 countries that we believe have strong growth potential based on their economic conditions, healthcare sectors and our global capabilities. We have increased our investment in infrastructure in these countries in order to maximize opportunities. Our Emerging Markets net sales represented 11 percent of our consolidated net sales in 2018 and 10 percent in 2017. In 2018, our Emerging Markets net sales grew 18.0 percent on a reported basis including operational net sales growth of 21.4 percent and the negative impact of 340 basis points from foreign currency fluctuations, as compared to 2017.

Results of Operations

Net Sales

The following table provides our net sales by business and the relative change in growth on a reported basis:

	Year Ended December 31,				
(in millions)	**2018**	**2017**	**2016**	**2018 versus 2017**	**2017 versus 2016**
Endoscopy	$ 1,762	$ 1,619	$ 1,440	8.8%	12.4%
Urology and Pelvic Health	1,245	1,124	1,005	10.8%	11.8%
MedSurg*	3,007	2,742	2,445	9.7%	12.2%
Cardiac Rhythm Management	1,951	1,895	1,850	2.9%	2.5%
Electrophysiology	311	278	243	12.1%	14.5%
Neuromodulation	779	635	556	22.7%	14.2%
Rhythm and Neuro*	3,041	2,808	2,649	8.3%	6.0%
Interventional Cardiology	2,590	2,419	2,281	7.1%	6.1%
Peripheral Interventions	1,187	1,081	1,011	9.8%	6.8%
Cardiovascular	3,777	3,500	3,292	7.9%	6.3%
Net Sales	**$ 9,823**	**$ 9,048**	**$ 8,386**	**8.6%**	**7.9%**

Refer to *Executive Summary* for further discussion of our net sales and a comparison of our 2018 and 2017 net sales.

In 2017, we generated net sales of $9.048 billion, as compared to $8.386 billion in 2016. This increase of $662 million, or 7.9 percent, included operational net sales growth of 7.8 percent and a positive impact of 10 basis points from foreign currency fluctuations, as compared to 2016. This increase was primarily due to increases in net sales from our Endoscopy business of $179 million, which included sales from our acquisition of EndoChoice Holdings, Inc. (EndoChoice) during the fourth quarter of 2016, from our Interventional Cardiology business of $138 million, primarily due to increased sales from our WATCHMAN™ LAAC Technology and from our acquisition of Symetis SA (Symetis) during the second quarter of 2017, and from our Urology and Pelvic Health business of $119 million.

Gross Profit

Our gross profit was $7.011 billion in 2018, $6.455 billion in 2017 and $5.962 billion in 2016. As a percentage of net sales, our gross profit increased to 71.4 percent in 2018, as compared to 71.3 percent in 2017 and 71.1 percent in 2016. The following is a reconciliation of our gross profit margins and a description of the drivers of the change from period to period:

	Gross Profit Margin
Year Ended December 31, 2016	**71.1%**
Manufacturing cost reductions	1.9%
Sales pricing and mix	0.1%
Inventory step-up due to acquisition accounting	(0.2)%
Net impact of foreign currency fluctuations	(1.3)%

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

All other, including other inventory charges and other period expense	(0.3)%
Year Ended December 31, 2017	**71.3%**
Manufacturing cost reductions	0.8%
Sales pricing and mix	(0.2)%
Inventory step-up due to acquisition accounting	(0.1)%
Net impact of foreign currency fluctuations	(0.8)%
All other, including other inventory charges and other period expense	0.4%
Year Ended December 31, 2018	**71.4%**

The primary factors contributing to the increase in our gross profit margin for 2018 as compared to 2017 were the positive impacts of cost reductions resulting from our process improvement programs and restructuring programs and favorable period expense, partially offset by negative impacts from foreign currency fluctuations. The primary factors contributing to the increase in our gross profit margin for 2017 as compared to 2016 were the positive impacts of cost reductions resulting from our process improvement programs and restructuring program, partially offset by negative impacts from foreign currency fluctuations and unfavorable period expense. Our gross profit margin in 2017 included unfavorable period expenses due to the charges we recorded in the first quarter of 2017 related to the voluntary removal of Lotus Valve Devices from global commercial and clinical sites.

Operating Expenses

The following table provides a summary of certain of our operating expenses:

	Year Ended December 31,					
	2018		2017		2016	
(in millions)	$	% of Net Sales	$	% of Net Sales	$	% of Net Sales
Selling, general and administrative expenses	$ 3,569	36.3%	$ 3,294	36.4%	$ 3,099	37.0%
Research and development expenses	1,113	11.3%	997	11.0%	920	11.0%
Royalty expense	70	0.7%	68	0.8%	79	0.9%

Selling, General and Administrative (SG&A) Expenses

In 2018, our *SG&A expenses* increased $275 million, or eight percent, as compared to 2017 and was 10 basis points lower as a percentage of net sales. This decrease in *SG&A expenses* as a percentage of net sales was primarily due to leverage from increased sales, as well as the benefit of our targeted initiatives focused on reducing *SG&A expenses* such as end-to-end business process streamlining and automation, including functional expansion of global shared service and robotic process utilization. In 2017, our *SG&A expenses* increased $195 million, or six percent, as compared to 2016 and were 60 basis points lower as a percentage of net sales. This decrease in *SG&A expenses* as a percentage of net sales was primarily driven by increased net sales, as well as the benefit of our targeted initiatives focused on reducing *SG&A expenses*.

Research and Development (R&D) Expenses

We remain committed to advancing medical technologies and investing in meaningful research and development projects across our businesses. In 2018, our *R&D expenses* increased $116 million, or 12 percent, as compared to 2017, and were 30 basis points higher as a percentage of net sales. In 2017, our *R&D expenses* increased $77 million, or eight percent, as compared to 2016, yet remained flat as a percentage of net sales. *R&D expenses* increased each year as a result of investments across our businesses in order to maintain a pipeline of new products that we believe will contribute to profitable sales growth.

Royalty Expense

In 2018, our *Royalty expense* increased $2 million, or three percent, as compared to 2017 and was 10 basis points lower as a percentage of net sales. The increase in *Royalty expense* in 2018, as compared to 2017, relates primarily to increased sales partially offset by expired royalties in certain countries.

In 2017, our *Royalty expense* decreased $11 million, or 14 percent, as compared to 2016 and was 10 basis points lower as a percentage of net sales. The decrease in *Royalty expense* in 2017 as compared to 2016 relates primarily to a renegotiated lower royalty rate structure on certain products.

The following table provides a summary of certain of our other operating expenses, which are excluded by management for purposes of evaluating operating performance:

	Year Ended December 31,		
(in millions)	**2018**	**2017**	**2016**
Amortization expense	$ 599	$ 565	$ 545
Intangible asset impairment charges	35	4	11
Contingent consideration expense (benefit)	(21)	(80)	29
Restructuring charges (credits)	36	37	28
Restructuring-related charges (credits)	59	58	50
Litigation-related net charges (credits)	103	285	804

Amortization Expense

In 2018, our *Amortization expense* increased $33 million, or six percent, as compared to 2017. In 2017, our *Amortization expense* increased $20 million, or four percent, as compared to 2016. The increases in each period were primarily due to amortizable intangible assets acquired as part of our recent acquisitions including Symetis in the second quarter of 2017, nVision Medical Corporation (nVision) and NxThera in the second quarter of 2018 and Augmenix in the fourth quarter of 2018.

Intangible Asset Impairment Charges

In 2018, 2017 and 2016, our *Intangible asset impairment charges* were immaterial. Refer to *Critical Accounting Estimates* for a discussion of key assumptions used in our goodwill and intangible asset impairment testing and future events that could have a negative impact on the recoverability of our goodwill and amortizable intangible assets.

Contingent Consideration Expense (Benefit)

In 2018 and 2017, we recorded net benefits, and in 2016, we recorded net expenses related to the change in fair value of our contingent consideration liability. Refer to *Note B – Acquisitions and Strategic Investments* to our consolidated financial statements contained in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional details related to our contingent consideration arrangements.

Restructuring and Restructuring-related Activities

In 2018, 2017 and 2016, our restructuring and restructuring-related charges remained relatively flat for all periods.

In November 2018, the Board of Directors approved, and we committed to, a new global restructuring program (the 2019 Restructuring Plan). The 2019 Restructuring Plan is expected to result in total pre-tax charges of approximately $200 million to $300 million and reduce gross annual pre-tax operating expenses by approximately $100 million to $150 million by the end of 2022 as program benefits are realized. The 2016 Restructuring Plan is expected to result in total pre-tax charges of approximately $275 million to $325 million and is expected to reduce gross annual expenses by approximately $165 million to $175 million by the end of 2020 as program benefits are realized. A substantial portion of the savings from both programs are being reinvested in strategic growth initiatives.

As of December 31, 2018, we have made cumulative cash payments of $197 million in association with our 2016 Restructuring Plan.

See *Note G – Restructuring-related Activities* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional details on our restructuring plans.

Litigation-related Net Charges (Credits)

In 2018, 2017 and 2016, our litigation-related net charges were primarily in connection with transvaginal surgical mesh product liability cases and claims.

We continue to assess certain litigation and claims to determine the amounts, if any, that management believes will be paid as a result of such claims and litigation, and therefore, additional losses may be accrued and paid in the future, which could materially

adversely impact our operating results, cash flows and/or our ability to comply with our debt covenants. Refer to *Note J – Commitments and Contingencies* to our consolidated financial statements contained in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional discussion of our material legal proceedings.

Interest Expense

The following table provides a summary of our *Interest expense* and average borrowing rate:

	Year Ended December 31,		
(in millions)	**2018**	**2017**	**2016**
Interest expense	$ (241)	$ (229)	$ (233)
Weighted average borrowing rate	3.6%	3.8%	4.0%

Refer to *Liquidity and Capital Resources* in this Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and *Note D – Hedging Activities and Fair Value Measurements* and *Note E – Borrowings and Credit Arrangements* to our consolidated financial statements contained in Item 8. Financial Statements and Supplementary Data of this Annual Report for information regarding our debt obligations.

Other, net

The following are the components of *Other, net*:

	Year Ended December 31,		
(in millions)	**2018**	**2017**	**2016**
Interest income	$ 3	$ 5	$ 5
Net foreign currency gain (loss)	11	(15)	(13)
Net gains (losses) on investments	155	(92)	(21)
Other income (expense), net	(14)	(22)	(8)
	$ 156	**$ (124)**	**$ (37)**

In 2018, we recorded gains of $184 million based on the difference between the book values and the fair values of our previously-held investments immediately prior to the acquisition dates, which aggregated to $251 million. We remeasured the fair value of each previously-held investment based on the implied enterprise value and allocation of purchase price consideration according to priority of equity interests. Gains and losses recorded on previously-held investments are excluded by management for purposes of evaluating operating performance.

Refer to *Note B – Acquisitions and Strategic Investments* to our consolidated financial statements contained in Item 8. Financial Statements and Supplementary Data of this Annual Report for information regarding our strategic investments.

Tax Rate

The following table provides a summary of our reported tax rate:

	Year Ended December 31,		
	2018	**2017**	**2016**
Reported tax rate	**(17.5)%**	**88.8 %**	**(95.9)%**

Impact of certain receipts/charges (1)	30.7 %	(75.8)%	108.3 %
	13.2 %	**13.0 %**	**12.4 %**

(1) These receipts/charges are taxed at different rates than our effective tax rate.

The change in our reported tax rate for 2018, as compared to 2017 and 2016, relates primarily to the impact of certain receipts and charges that are taxed at different rates than our effective tax rate. These receipts and charges included intangible asset impairment charges, acquisition-related items, restructuring and restructuring-related items, litigation-related items, as well as certain discrete tax items. Included in the discrete tax items were the effective settlement of our transfer pricing dispute with the Internal Revenue Service (IRS) for the 2001 through 2010 tax years, the conclusion of the IRS examinations of our 2011 through 2013 tax years, and the final impact of the Tax Cuts and Jobs Act (TCJA), enacted on December 22, 2017.

In 2017, these receipts and charges included intangible asset impairment charges, acquisition-related items, restructuring and restructuring-related items, litigation-related items and certain investment impairments. Our reported tax rate for 2017 was also affected by discrete items primarily related to the TCJA.

In 2016, these receipts and charges included intangible asset impairment charges, acquisition-related items, restructuring and restructuring-related items and litigation-related items. Our reported tax rate for 2016 was also affected by discrete items primarily related to the resolution of various uncertain tax positions through settlement or expiration of statute, offset by a charge related to changes in state apportionment.

During 2010 and 2011, we received Notices of Deficiency from the Internal Revenue Service (IRS) reflecting proposed audit adjustments for Guidant Corporation (Guidant) for its 2001 through 2006 tax years and our 2006 and 2007 tax years. The total incremental tax liability asserted by the IRS for the applicable periods was $1.162 billion plus interest. The primary issue in dispute for all years was the transfer pricing associated with the technology license agreements between domestic and foreign subsidiaries of Guidant. In addition, the IRS proposed adjustments in connection with the financial terms of our Transaction Agreement with Abbott Laboratories pertaining to the sale of Guidant's vascular intervention business to Abbott Laboratories in April 2006. During 2014, we received a Revenue Agent Report (RAR) from the IRS reflecting significant proposed audit adjustments to our 2008, 2009 and 2010 tax years based upon the same transfer pricing methodologies that the IRS applied to our 2001 through 2007 tax years.

We contested in U.S. Tax Court the proposed adjustments from the IRS for Guidant for its 2001 through 2006 tax years and our 2006 and 2007 tax years related to its audit of our transfer pricing methodologies. During 2016, we entered a Stipulation of Settled Issues with the IRS intended to resolve all of the aforementioned transfer pricing issues, as well as issues related to our 2006 transaction with Abbott Laboratories. This stipulation was contingent upon the IRS Office of Appeals applying the same basis of settlement to all transfer pricing issues for the 2008 through 2010 tax years.

In the second quarter of 2018, a decision was entered by the U.S. Tax Court resolving all disputes related to the transfer pricing issues for Guidant for its 2001 through 2006 tax years and our 2006 and 2007 tax years as well as the tax issues related to our 2006 transaction with Abbott Laboratories. Additionally, we resolved all issues with the IRS Office of Appeals for our 2008 through 2010 tax years, including the transfer pricing issue and other unrelated issues. The final settlement calculation included certain elections made in these relevant years and resulted in a final net tax payment of $303 million plus $307 million of estimated interest, which was remitted in the second quarter of 2018. Due to the final settlement of these disputes, we recorded a net tax benefit of $250 million in 2018.

In the fourth quarter of 2018, we received a RAR from the IRS for our 2011 through 2013 tax years. The RAR reflected transfer pricing adjustments consistent with the basis of settlement for all transfer pricing issues agreed to in the Stipulation of Settled Issues. We remitted $93 million to the IRS in the fourth quarter of 2018 reflecting the net balance of tax and interest due for these years after consideration of amounts owed to us by the IRS. Due to the resolution of these tax years, we recorded a net tax benefit of $90 million.

See *Note I - Income Taxes* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional details on our tax rate.

Liquidity and Capital Resources

Based on our current business plan, we believe our existing balance of *Cash and cash equivalents*, future cash generated from operations, access to capital markets and existing credit facilities will be sufficient to fund our operations, invest in our infrastructure, pay our legal-related liabilities, pay taxes due, fund possible mergers and/or acquisitions and service and repay our existing debt. Please refer to *Contractual Obligations and Commitments* below for additional details on our future payment obligations and commitments.

As of December 31, 2018, we had $146 million of *Cash and cash equivalents* on hand, comprised of $13 million invested in money market and government funds and $133 million in interest bearing and non-interest-bearing bank accounts. We invest excess cash on hand in short-term financial instruments that earn at market interest rates while mitigating principal risk through instrument and counterparty diversification, as well as what we believe to be prudent instrument selection. We limit our direct exposure to securities in any one industry or issuer. We also have access to our $2.750 billion commercial paper program, which is backed by our 2018 revolving credit facility entered into on December 19, 2018. As of December 31, 2018, we had $1.248 billion in commercial paper debt outstanding resulting in an additional $1.502 billion of available liquidity.

For the purpose of funding the proposed BTG Acquisition, as described below, we have access to a bridge facility entered into on November 20, 2018 (Bridge Facility), which is comprised of a £3.115 billion debt bridge facility and a £200 million cash bridge facility for an aggregate principal amount of £3.315 billion. Borrowings from the debt bridge facility mature in 364 days from the date of the first borrowing under the Bridge Facility, and borrowings from the cash bridge facility mature 90 days from the date of the first borrowing under the Bridge Facility. In addition, on December 19, 2018, we entered into a $1.000 billion two-year delayed draw term loan credit facility, maturing in two years from the date of the closing of the proposed BTG Acquisition (Two-Year Delayed Draw Term Loan) and a $1.000 billion three-year delayed draw term loan credit facility, maturing in three years from the date of the closing of the proposed BTG Acquisition (Three-Year Delayed Draw Term Loan). As of December 31, 2018, we had no amounts borrowed under the Bridge Facility, the Two-Year Delayed Draw Term Loan or the Three-Year Delayed Draw Term Loan. In December 2018, in connection with our new term loans and currency hedging activities, we reduced the debt bridge facility by an aggregate amount of £1.569 billion to a remaining available amount of £1.546 billion.

On December 19, 2018 and effective on December 20, 2018, we terminated our $400 million credit and security facility secured by our U.S. trade receivables. We had no amounts outstanding under this facility as of December 31, 2017.

For additional information on our credit facilities, refer to *Note E – Borrowings and Credit Arrangements* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report.

The following provides a summary and description of our net cash inflows (outflows):

	Year Ended December 31,		
(in millions)	**2018**	**2017**	**2016**
Cash provided by (used for) operating activities	$ 310	$ 1,426	$ 1,182
Cash provided by (used for) investing activities	(1,921)	(1,010)	(887)
Cash provided by (used for) financing activities	1,432	110	(206)
Cash provided by (used for) operating activities	$ 310	$ 1,426	$ 1,182
Less: Purchases of property, plant and equipment	316	319	376
Add: Proceed on disposals of property, plant and equipment	14	—	29
Free cash flow	8	1,107	835
Add: Restructuring and restructuring-related payments	89	72	52
Add: Acquisitions-related payments	205	95	108
Add: Certain discrete tax payments (refunds/credits)	977	(239)	(74)
Add: Litigation-related settlements	791	694	701
Adjusted free cash flow[2]	$ 2,070	$ 1,729	$ 1,622

Operating Activities

In 2018, cash from operating activities decreased $1.116 billion, or 78 percent, as compared to 2017. This decrease was primarily due to the IRS tax settlement in 2018.

In 2017, cash from operating activities increased $244 million, or 21 percent, as compared to 2016. This increase was primarily driven by the increase in operating profit for 2017 compared to 2016.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

[2]Adjusted free cash flow, which excludes certain items required by U.S. GAAP is not prepared in accordance with U.S. GAAP and should not be considered in isolation from, or as a replacement for, the most directly comparable GAAP measure. Refer to *Additional Information* for a discussion of management's use of non-GAAP financial measures.

Investing Activities

In 2018, cash used for investing activities included $1.448 billion of payments, net of cash acquired, for acquisitions including Augmenix, NxThera, Cryterion Medical, Inc., Claret and nVision, $316 million of payments for purchases of property, plant and equipment and $172 million of payments related to investments and acquisitions of certain technologies, including our $90 million investment in Millipede, Inc. in the first quarter of 2018.

In 2017, cash used for investing activities included $560 million of payments, net of cash acquired, for acquisitions including Symetis and Apama Medical Inc. (Apama), $319 million of payments for purchases of property, plant and equipment, including amounts to complete our manufacturing plant in Malaysia and $131 million of payments related to investments and acquisitions of certain technologies.

In 2016, cash used for investing activities included $408 million of payments net of cash acquired, for acquisitions including EndoChoice, $376 million in purchases of property, plant and equipment and $132 million of payments related to investments and acquisitions of certain technologies, partially offset by proceeds from the sale of one of two buildings located in Quincy, Massachusetts for $29 million.

Financing Activities

Our cash flows from financing activities reflect issuances and repayments of debt, including our commercial paper program and cash used for new share settlement and stock issuances related to our equity incentive programs, as discussed in *Note K - Stockholders' Equity* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report. Additionally, our financing activities included $19 million of contingent payments in 2018, $33 million of payments in 2017 and $65 million of payments in 2016 associated with our previous acquisitions.

Our liquidity plans are subject to a number of risks and uncertainties, including those described in Item 1A. Risk Factors of this Annual Report, some of which are outside our control. Macroeconomic conditions, adverse litigation outcomes and other risks and uncertainties could limit our ability to successfully execute our business plans and adversely affect our liquidity plans.

Debt

The following table presents the current and long-term portions of our total debt:

	As of	
(in millions)	**December 31, 2018**	**December 31, 2017**
Current debt obligations	$ 2,253	$ 1,801
Long-term debt	4,803	3,815
Total debt	**$ 7,056**	**$ 5,616**

The following table presents the portions of our total debt that are comprised of fixed and variable rate debt instruments, which are presented on an amortized cost basis:

	As of	
(in millions)	**December 31, 2018**	**December 31, 2017**
Fixed-rate debt instruments	$ 4,797	$ 4,414
Variable rate debt instruments	2,259	1,202
Total debt	**$ 7,056**	**$ 5,616**

As of and through December 31, 2018, we were in compliance with all the required covenants related to our debt obligations. For additional details related to our debt obligations, including our debt covenant requirements, refer to *Note E – Borrowings and Credit Arrangements* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report.

Equity

During 2018 we received $101 million in proceeds from stock issuances related to our stock option and employee stock purchase plans, as compared to $85 million in 2017 and $111 million 2016. Proceeds from the exercise of employee stock options and employee stock purchases vary from period to period based upon, among other factors, fluctuations in the trading price of our common stock and in the exercise and stock purchase patterns of employees.

We did not repurchase any shares of our common stock during 2018, 2017, or 2016. As of December 31, 2018, we had remaining approximately $535 million authorized under our 2013 share repurchase program. There were approximately 248 million shares in treasury as of December 31, 2018 and December 31, 2017.

Stock-based compensation expense related to our stock ownership plans was $140 million in 2018, $127 million in 2017 and $116 million in 2016. Stock-based compensation expense varies from period to period based upon, among other factors, the timing, number and fair value of awards granted during the period, forfeiture levels related to unvested awards and employee contributions to our employee stock purchase plan.

Contractual Obligations and Commitments

The following table provides a summary of certain information concerning our obligations and commitments to make future payments and is based on conditions in existence as of December 31, 2018:

(in millions)	2019	2020	2021	2022	2023	Thereafter	Total
Debt obligations (1)	$ 2,248	$ 1,450	$ —	$ 500	$ 450	$ 2,400	$ 7,048
Interest payments (2)	245	190	156	147	139	928	1,804
Lease obligations (2)	73	61	47	39	31	111	362
Purchase obligations (2)	362	23	12	3	2	7	409
Minimum royalty obligations (2)	4	5	3	2	2	2	17
Legal reserves	712	—	—	—	—	—	712
One-time transition tax	9	40	40	40	75	225	429
Acquisition (3)	325	—	—	—	—	—	325
	$ 3,977	**$ 1,768**	**$ 257**	**$ 731**	**$ 699**	**$ 3,673**	**$ 11,106**

(1) Debt obligations are comprised of our senior notes, term loan and commercial paper outstanding as of December 31, 2018. This does not include unamortized debt issuance discounts, deferred financing costs and gain on fair value hedges or capital lease obligations. Refer to *Note E – Borrowings and Credit Arrangements* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional information.

(2) In accordance with U.S. GAAP, these obligations relate to expenses associated with future periods and are not reflected in our consolidated balance sheets. Interest payments included above are calculated based on rates and required fees applicable to our outstanding debt obligations as of December 31, 2018 described in *Note E – Borrowings and Credit Arrangements* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report. Interest payments above do not include interest on variable rate debt instruments. Lease obligations included an immaterial amount of capital leases which are included in our consolidated balance sheets as of December 31, 2018.

(3) On January 29, 2019, we announced the closing of our acquisition of Millipede, Inc. (Millipede) after exercising our option to acquire the remaining shares of Millipede in the fourth quarter of 2018 upon the recent successful completion of a first-in-human clinical study. The transaction price for the remaining stake consists of an upfront cash payment of $325 million, which was paid in January 2019 and included in the table above, and up to an additional $125 million payment upon achievement of a commercial milestone, which has not been achieved and is not included in the table above. Refer to *Note B – Acquisitions and Strategic Investments* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional information.

The amounts in the table above with respect to lease obligations represent amounts pursuant to contractual arrangements for the lease of property, plant and equipment used in the normal course of business. Purchase obligations relate primarily to non-cancellable inventory commitments and capital expenditures entered in the normal course of business. Royalty obligations reported above represent minimum contractual obligations under our current royalty agreements.

The table above does not include:

- Our long-term liability for legal matters that are probable and estimable of $217 million due to the timing of payment being uncertain. Refer to *Note J – Commitments and Contingencies* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report for more information,

- Unrecognized tax benefits, accrued interest and penalties and other related items totaling $266 million because the timing of their future cash settlement is uncertain and tax payments and interest totaling $5 million related to state obligations of recently settled IRS tax years to be remitted in 2019. Refer to *Note I - Income Taxes* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report for more information,

- Our recommended offer to acquire BTG plc (BTG) announced on November 20, 2018 for an upfront cash payment of approximately £3.311 billion or approximately $4.225 billion based on the exchange rate of U.S. $1.28: £1.00 on December 31, 2018 (the proposed BTG Acquisition). Refer to *Note B – Acquisitions and Strategic Investments* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report for more information,

- With certain of our acquisitions, we acquired IPR&D projects that require future funding to complete the projects. We estimate that the total remaining R&D cost to complete acquired IPR&D projects is between $55 million and $65 million. Net cash inflows from the projects currently in development are expected to commence in 2018 and will continue through 2031, following the respective launches of these technologies in the U.S., Europe and Japan. Certain of our acquisitions also involve the potential payment of contingent consideration, but the timing and amounts are uncertain. See *Note B – Acquisitions and Strategic Investments* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report for more information, and

- The $275 million purchase agreement that on September 12, 2018, Channel Medsystems, Inc. (Channel) filed a complaint in Delaware Chancery Court against us for alleged breach of our purchase agreement with Channel. Refer to *Note J – Commitments and Contingencies* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report for more information.

Legal Matters

For a discussion of our material legal proceedings see *Note J – Commitments and Contingencies* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report.

Critical Accounting Policies and Estimates

Our financial results are affected by the selection and application of accounting policies and methods. We have adopted accounting policies to prepare our consolidated financial statements in conformity with U.S. GAAP.

To prepare our consolidated financial statements in accordance with U.S. GAAP, management makes estimates and assumptions that may affect the reported amounts of our assets and liabilities, including our contingent liability, as of the date of our financial statements and the reported amounts of our revenues and expenses during the reporting periods. Our actual results may differ from these estimates. We consider estimates to be critical (i) if we are required to make assumptions about material matters that are uncertain at the time of estimation or (ii) if materially different estimates could have been made or it is reasonably likely that the accounting estimate will change from period to period. The following are areas considered to be critical and require management's judgment: Revenue Recognition, Bad Debt Reserves, Inventory Provisions, Valuation of Intangible Assets and Contingent Consideration Liability, Goodwill Valuation, Legal and Product Liability Accruals and Income Taxes.

See *Note A – Significant Accounting Policies* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional information related to our accounting policies and our consideration of these critical accounting areas. In addition, see *Note B – Acquisitions and Strategic Investments* and *Note C - Goodwill and Other Intangible Assets* for further discussion of the valuation of goodwill and intangible assets and contingent consideration, *Note I - Income Taxes* for further discussion of income tax related matters, *Note J – Commitments and Contingencies* for further discussion of legal and product liability matters and *Note O – Revenue* for further discussion of revenue recognition.

Revenue Recognition

Deferred Revenue

We record a contract liability, or deferred revenue, when we have an obligation to provide a product or service to the customer and payment is received or due in advance of our performance. When we sell a device with a future service obligation, we defer revenue on the unfulfilled performance obligation and recognize this revenue over the related service period. Many of our Cardiac Rhythm Management (CRM) product offerings combine the sale of a device with our LATITUDE™ Patient Management System, which represents a future service obligation. Generally, we do not have observable evidence of the standalone selling price related

to our future service obligations; therefore, we estimate the selling price using an expected cost plus a margin approach. We allocate the transaction price using the relative standalone selling price method. The use of alternative estimates could result in a different amount of revenue deferral.

Contract liabilities are classified within *Other current liabilities* and *Other long-term liabilities* on our accompanying consolidated balance sheets. Our contractual liabilities are primarily composed of deferred revenue related to the LATITUDE Patient Management System. Revenue is recognized over the average service period which is based on device and patient longevity.

Variable Consideration

We generally allow our customers to return defective, damaged and, in certain cases, expired products for credit. We base our estimate for sales returns upon historical trends and record the amount as a reduction to revenue when we sell the initial product. In addition, we may allow customers to return previously purchased products for next-generation product offerings. For these transactions, we defer recognition of revenue on the sale of the earlier generation product based upon an estimate of the amount of product to be returned when the next-generation products are shipped to the customer. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls and variation in product utilization all affect our estimates related to sales returns and could cause actual returns to differ from these estimates.

We also offer sales rebates and discounts to certain customers. We treat sales rebates and discounts as a reduction of revenue and classify the corresponding liability as current. We estimate rebates for products where there is sufficient historical information available to predict the volume of expected future rebates. If we are unable to reasonably estimate the expected rebates, we record a liability for the maximum rebate percentage offered.

Post Implant Services

We provide non-contractual services to customers to ensure the safe and effective use of certain implanted devices. Since our modified retrospective adoption of FASB ASC Topic 606, *Revenue from Contracts with Customers* on January 1, 2018, because the revenue related to the immaterial services is recognized before they are delivered, we forward accrue the costs to provide these services at the time the devices are sold. We record these costs to *Selling, general and administrative expenses*. We estimate the amount of time spent by our representatives performing these services and their compensation throughout the device life to determine the service cost. Changes to our business practice or the use of alternative estimates could result in a different amount of accrued cost. Refer to *Note A – Significant Accounting Policies* and *Note O – Revenue* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report for further information on our adoption of FASB ASC Topic 606 and our revenue recognition accounting policies.

Inventory Provisions

We base our provisions for excess, expired and obsolete inventory primarily on our estimates of forecasted net sales. A significant change in the timing or level of demand for our products as compared to forecasted amounts may result in recording additional provisions for excess, expired and obsolete inventory in the future. Further, the industry in which we participate is characterized by rapid product development and frequent new product introductions. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls and variation in product utilization all affect our estimates related to excess, expired and obsolete inventory.

Valuation of Intangible Assets and Contingent Consideration Liability

We base the fair value of identifiable intangible assets acquired in a business combination, including IPR&D, on detailed valuations that use information and assumptions provided by management, which consider management's best estimates of inputs and assumptions that a market participant would use. Further, for those arrangements that involve potential future contingent consideration, we record on the date of acquisition a liability equal to the fair value of the estimated additional consideration we may be obligated to make in the future. We re-measure this liability each reporting period and record changes in the fair value through a separate line item within our consolidated statements of operations. Increases or decreases in the fair value of the contingent consideration liability can result from changes in discount rates, periods, timing and amount of projected revenue or timing or likelihood of achieving regulatory, revenue or commercialization-based milestones. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, cash flows, discount rates, useful life or probability of achieving clinical, regulatory or revenue-based milestones could result in different purchase price allocations and recognized amortization expense and contingent consideration expense or benefit in current and future periods.

We review intangible assets subject to amortization quarterly to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or adjustment to the remaining useful life. If we determine it is more likely than not that the asset is impaired based on our qualitative assessment of impairment indicators, we test the intangible asset for recoverability. If the carrying value of the intangible asset is determined not recoverable, we will write the carrying value down to fair value in the period identified. We calculate fair value of our intangible assets as the present value of estimated future cash flows we expect to generate from the asset using a risk-adjusted discount rate. The use of alternative assumptions, including estimated cash flows, discount rates and alternative estimated remaining useful lives could result in different calculations of impairment.

In addition, we test our indefinite-lived intangible assets at least annually for impairment and reassess their classification as indefinite-lived assets, or more frequently if change in circumstance or indicators exist. We assess qualitative factors to determine whether the existence of events and circumstances indicate that it is more likely than not that our indefinite-lived intangible assets are impaired. If we conclude that it is more likely than not that the asset is impaired, we then determine the fair value of the intangible asset and perform the quantitative impairment test by comparing the fair value with the carrying value in accordance with FASB ASC Topic 350, *Intangibles - Goodwill and Other* (FASB ASC Topic 350). If the carrying value exceeds the fair value of the indefinite-lived intangible asset, we write the carrying value down to fair value. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, cash flows and discount rates could result in different fair value estimates.

Goodwill Valuation

We allocate any excess purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination to goodwill. We test our goodwill balances during the second quarter of each year for impairment, or more frequently if indicators are present or changes in circumstances suggest that impairment may exist. We assess goodwill for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment, referred to as a component. For our 2018, 2017 and 2016 annual impairment assessment, we identified seven reporting units: Interventional Cardiology, Peripheral Interventions, Cardiac Rhythm Management, Electrophysiology, Endoscopy, Urology and Pelvic Health and Neuromodulation. Beginning in 2016, we aggregated the Cardiac Rhythm Management and Electrophysiology reporting units, components of the Rhythm Management operating segment, based on the criteria prescribed in FASB ASC Topic 350. These reporting units were aggregated due to a reorganization that commenced in 2015 that resulted in integrated leadership, shared resources and consolidation of certain sites in 2016.

Refer to *Note A – Significant Accounting Policies* to our consolidated financial statements contained in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional details related to our annual goodwill impairment assessments performed in 2018, 2017 and 2016.

Although we use consistent methodologies in developing the assumptions and estimates underlying the fair value calculations used in our impairment tests, these estimates are uncertain by nature and can vary from actual results. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, cash flows and discount rates could result in different fair value estimates.

Future events that could have a negative impact on the levels of excess fair value over carrying value of our reporting units include, but are not limited to, the following:

- decreases in estimated market sizes or market growth rates due to greater-than-expected declines in procedural volumes, pricing pressures, reductions in reimbursement levels, product actions and/or competitive technology developments,
- declines in our market share and penetration assumptions due to increased competition, an inability to develop or launch new and next-generation products and technology features in line with our commercialization strategies and market and/or regulatory conditions that may cause significant launch delays or product recalls,
- decreases in our forecasted profitability due to an inability to implement successfully and achieve timely and sustainable cost improvement measures consistent with our expectations,
- negative developments in intellectual property litigation that may impact our ability to market certain products or increase our costs to sell certain products,

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

- the level of success of ongoing and future research and development efforts, including those related to recent acquisitions and increases in the research and development costs necessary to obtain regulatory approvals and launch new products,

- the level of success in managing the growth of acquired companies, achieving sustained profitability consistent with our expectations, establishing government and third-party payer reimbursement, supplying the market and increases in the costs and time necessary to integrate acquired businesses into our operations successfully,
- changes in our reporting units or in the structure of our business as a result of future reorganizations, acquisitions or divestitures of assets or businesses and
- increases in our market-participant risk-adjusted weighted average cost of capital (WACC) and increases in our market-participant tax rate and/or changes in tax laws or macroeconomic conditions.

Negative changes in one or more of these factors, among others, could result in future impairment charges.

Refer to *Note C - Goodwill and Other Intangible Assets* to our consolidated financial statements contained in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional details related to our annual goodwill balances.

Legal and Product Liability Accruals

In the normal course of business, we are involved in various legal and regulatory proceedings, including intellectual property, breach of contract, securities litigation and product liability suits. In some cases, the claimants seek damages, as well as other relief, which, if granted, could require significant expenditures or impact our ability to sell our products. We accrue anticipated costs of settlement, damages, losses for product liability claims and, under certain conditions, costs of defense, based on historical experience or to the extent specific losses are probable and estimable. Otherwise, we expense these costs as incurred. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue the minimum amount of the range. Litigation and product liability matters are inherently uncertain, and the outcomes of individual matters are difficult to predict and quantify. As such, significant judgment is required in determining our legal and product liability accruals. Our estimates related to our legal and product liability accruals may change as additional information becomes available to us, including information related to the nature or existence of claims against us, trial court or appellate proceedings, and mediation, arbitration or settlement proceedings.

Income Taxes

We establish reserves when we believe that certain positions are likely to be challenged despite our assertion that our tax return positions are fully supportable. The calculation of our tax liabilities involves significant judgment based on individual facts, circumstances and information available in addition to applying complex tax regulations in various jurisdictions across our global operations. Under U.S. GAAP, in order to recognize an uncertain tax benefit, the taxpayer must determine it is more likely than not the position will be sustained, and the measurement of the benefit is calculated as the largest amount that is more than 50 percent likely to be realized upon resolution of the benefit. Although we believe that we have adequately provided for liabilities resulting from tax assessments by taxing authorities, positions taken by these tax authorities could have a material impact on our effective tax rate, results of operations, financial position and/or cash flows.

As part of the Tax Cut and Jobs Act of 2017, we are subject to a territorial tax system in which we are required to make an accounting policy in providing for tax on Global Intangible Low Taxed Income (GILTI) earned by certain foreign subsidiaries. We have elected to treat the impact of GILTI as a period cost and will be reported as a part of continuing operations.

New Accounting Pronouncements

See *Note A – Significant Accounting Policies* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional information on standards implemented since December 31, 2017 and *Note Q - New Accounting Pronouncements* to our consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report for additional information on standards to be implemented.

Additional Information

Use of Non-GAAP Financial Measures

To supplement our consolidated financial statements presented on a GAAP basis, we disclose certain non-GAAP financial measures, including adjusted net income (earnings) and adjusted net income (earnings) per share that exclude certain amounts, operational net sales growth that exclude the impact of foreign currency fluctuations and adjusted free cash flow that excludes certain amounts. These non-GAAP financial measures are not in accordance with generally accepted accounting principles in the United States and should not be considered in isolation from or as a replacement for the most directly comparable GAAP financial measures. Further, other companies may calculate these non-GAAP financial measures differently than we do, which may limit the usefulness of those measures for comparative purposes.

To calculate adjusted net income (earnings) and adjusted net income (earnings) per share we exclude certain charges (credits) from GAAP net income as detailed below. Amounts are presented after-tax using our effective tax rate, unless the amount is a significant unusual or infrequently occurring item in accordance with FASB ASC section 740-270-30, "General Methodology and Use of Estimated Annual Effective Tax Rate." The GAAP financial measure most directly comparable to adjusted net income is GAAP net income (loss) and the GAAP financial measure most directly comparable to adjusted net income per share is GAAP net income (loss) per share.

To calculate operational net sales, which exclude the impact of foreign currency fluctuations, we convert actual net sales from local currency to U.S. dollars using constant foreign currency exchange rates in the current and prior periods. The GAAP financial measure most directly comparable to operational growth rate percentages is growth rate percentages using net sales on a GAAP basis.

To calculate adjusted free cash flow, we exclude the cash component of certain charges (credits) that are also excluded from adjusted net income (earnings) as well as any cash tax benefits of such charges, as detailed below. In addition, we exclude tax settlements payments that relate to prior periods. The GAAP measure that is most directly comparable to adjusted free cash flow is free cash flow on a GAAP basis. Free cash flow on a GAAP basis is calculated by subtracting net purchases of property, plant and equipment from cash provided by operating activities.

Reconciliations of each of these non-GAAP financial measures to the corresponding GAAP financial measure are included in the relevant sections of this Annual Report.

Management uses these supplemental non-GAAP financial measures to evaluate performance period over period, to analyze the underlying trends in our business, to assess our performance relative to our competitors and to establish operational goals and forecasts that are used in allocating resources. In addition, management uses these non-GAAP financial measures to further its understanding of the performance of our operating segments. The adjustments excluded from our non-GAAP financial measures are consistent with those excluded from our operating segments' measures of net sales and profit or loss. These adjustments are excluded from the segment measures reported to our chief operating decision maker that are used to make operating decisions and assess performance.

We believe that presenting adjusted net income, adjusted net income per share that exclude certain amounts, operational net sales growth that exclude the impact of changes in foreign currency exchange rates, and adjusted free cash flow that excludes certain amounts, in addition to the corresponding GAAP financial measures, provides investors greater transparency to the information used by management for its operational decision-making and allows investors to see our results "through the eyes" of management. We further believe that providing this information assists our investors in understanding our operating performance and the methodology used by management to evaluate and measure such performance.

The following is an explanation of each of the adjustments that management excluded as part of these non-GAAP financial measures as well as reasons for excluding each of these individual items. In each case, management has excluded the item for purposes of calculating the relevant non-GAAP financial measure to facilitate an evaluation of our current operating performance and a comparison to our past operating performance:

Adjusted Net Income, Adjusted Net Income per Share and Adjusted Free Cash Flow

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

- Amortization expense - We record intangible assets at historical cost and amortize them over their estimated useful lives. Amortization expense is excluded from management's assessment of operating performance and is also excluded from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.

- Intangible asset impairment charges - This amount represents write-downs of certain intangible asset balances during 2018, 2017 and 2016.We review intangible assets subject to amortization quarterly to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment and test our indefinite-lived intangible assets at least annually for impairment. If we determine the carrying value of the amortizable intangible asset is not recoverable or we conclude that it is more likely than not that the indefinite-live asset is impaired, we will write the carrying value down to fair value in the period identified. Impairment charges are excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.

- Acquisition-related net charges (credits) or payments- These adjustments may consist of (a) contingent consideration fair value adjustments; (b) gains on previously held investments; (c) due diligence, deal fees, inventory step-up amortization, integration and exit costs, other fees, and accelerated compensation expense; and (d) separation costs and gains primarily associated with the sale of a business or portion of a business. The contingent consideration adjustments represent accounting adjustments to state contingent consideration liabilities at their estimated fair value. These adjustments can be highly variable depending on the assessed likelihood and amount of future contingent consideration payments. Due diligence, deal fees, inventory step-up amortization, integration and exit costs include legal, tax, severance and other expenses associated with prior and potential future acquisitions and divestitures that can be highly variable and not representative of ongoing operations. Separation costs and gains/losses on the sale of a business unit would represent those costs associated with a divestiture and are not representative of ongoing operations. Acquisition-related net charges (credits) are excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.

- Restructuring and restructuring-related net charges (credits) or payments - These adjustments primarily represent compensation-related charges, fixed asset write-offs, contract cancellations, project management fees and other direct costs associated with our restructuring plans. These restructuring plans each consist of distinct initiatives that are fundamentally different from our ongoing, core cost reduction initiatives in terms of, among other things, the frequency with which each action is performed and the required planning, resourcing, cost and timing. Examples of such initiatives include the movement of business activities, facility consolidations and closures and the transfer of product lines between manufacturing facilities, which, due to the highly regulated nature of our industry, requires a significant investment in time and cost to create duplicate manufacturing lines, run product validations and seek regulatory approvals. Restructuring initiatives take place over a defined timeframe and have a distinct project timeline that begins subsequent to approval by our Board of Directors. In contrast to our ongoing cost reduction initiatives, restructuring initiatives typically result in duplicative cost and exit costs over this period of time, are one-time shut downs or transfers and are not considered part of our core, ongoing operations. These restructuring plans are incremental to the core activities that arise in the ordinary course of our business. Restructuring and restructuring-related net charges (credits) are excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.

- Litigation-related net charges (credits) or payments - These adjustments include certain significant product liability and other litigation-related charges and credits. We record these charges and credits, which we consider to be unusual or infrequent and significant, within the litigation-related charges line in our consolidated statements of operations; all other legal and product liability charges, credits and costs are recorded within selling general and administrative expenses. Litigation-related net charges (credits) are excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.

- Investment impairment charges - These amounts represent write-downs relating to our investment portfolio that are considered unusual or infrequent and significant. Each reporting period, we evaluate our investments to determine if there are any events or circumstances that are likely to have a significant adverse effect on the fair value of the investment. If we identify an impairment indicator, we will estimate the fair value of the investment and compare it to its carrying value and determine if the impairment is other-than-temporary. For other-than-temporary impairments, we recognize an impairment loss equal to the difference between an investment's carrying value and its fair value. Certain investment impairment charges are excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.

- Discrete tax items - These items represent adjustments of certain tax positions including those which a) are related to the finalization of the enactment date impact of the TCJA, and, or b) were a benefit resulting from the finalization of the IRS Stipulation of Settled Issues consistent with the manner in which the tax reserves were originally booked. These adjustments are not indicative of expected ongoing operating results. Certain discrete tax items are excluded

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.

Operational Net Sales Excluding the Impact of Foreign Currency Fluctuations

- The impact of foreign currency fluctuations is highly variable and difficult to predict. Accordingly, management may exclude the impact of foreign currency fluctuations for purposes of reviewing the net sales and growth rates to facilitate an evaluation of our current operating performance and a comparison to our past operating performance.

Rule 10b5-1 Trading Plans by Executive Officers

Periodically, certain of our executive officers adopt written stock trading plans in accordance with Rule 10b5-1 under the Exchange Act and our own Stock Trading Policy. A Rule 10b5-1 Trading Plan is a written document that pre-establishes the amount, prices and dates (or formulas for determining the amounts, prices and dates) of future purchases or sales of our stock, including shares issued upon exercise of stock options or vesting of deferred stock units. These plans are entered into at a time when the person is not in possession of material non-public information about our company. We disclose details regarding individual Rule 10b5-1 Trading Plans on the Investor Relations section of our website.

Management's Annual Report on Internal Control over Financial Reporting

As the management of Boston Scientific Corporation, we are responsible for establishing and maintaining adequate internal control over financial reporting. We designed our internal control process to provide reasonable assurance to management and the Board of Directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

We assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control–Integrated Framework (2013 framework). Based on our assessment, we believe that, as of December 31, 2018, our internal control over financial reporting is effective at a reasonable assurance level based on these criteria.

Ernst & Young LLP, an independent registered public accounting firm, has issued an audit report on the effectiveness of our internal control over financial reporting. This report, in which they expressed an unqualified opinion, is included below.

/s/ Michael F. Mahoney

Michael F. Mahoney
President and Chief Executive Officer

/s/ Daniel J. Brennan

Daniel J. Brennan
Executive Vice President and Chief Financial Officer

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Boston Scientific Corporation

Opinion on Internal Control over Financial Reporting

We have audited Boston Scientific Corporation's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Boston Scientific Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the 2018 consolidated financial statements of the Company and our report dated February 19, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP
Boston, Massachusetts

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

February 19, 2019

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We develop, manufacture and sell medical devices globally and our earnings and cash flows are exposed to market risk from changes in currency exchange rates and interest rates. We address these risks through a risk management program that includes the use of derivative financial instruments. We operate the program pursuant to documented corporate risk management policies. We do not enter derivative transactions for speculative purposes. Gains and losses on derivative financial instruments substantially offset losses and gains on underlying hedged exposures. Furthermore, we manage our exposure to counterparty risk on derivative instruments by entering into contracts with a diversified group of major financial institutions and by actively monitoring outstanding positions.

Our currency risk consists primarily of foreign currency denominated firm commitments, forecasted foreign currency denominated intercompany and third-party transactions and net investments in certain subsidiaries. We use both nonderivative (primarily European manufacturing operations) and derivative instruments to manage our earnings and cash flow exposure to changes in currency exchange rates. We had currency derivative instruments outstanding in the contract amount of $11.326 billion as of December 31, 2018 and $5.923 billion as of December 31, 2017. A ten percent appreciation in the U.S. dollar's value relative to the hedged currencies would increase the derivative instruments' fair value by $181 million as of December 31, 2018 as compared to $321 million as of December 31, 2017. A ten percent depreciation in the U.S. dollar's value relative to the hedged currencies would decrease the derivative instruments' fair value by $222 million as of December 31, 2018 as compared to $421 million as of December 31, 2017. Any increase or decrease in the fair value of our currency exchange rate sensitive derivative instruments would be substantially offset by a corresponding decrease or increase in the fair value of the hedged underlying asset, liability or forecasted transaction, resulting in minimal impact on our consolidated statements of operations.

Our interest rate risk relates primarily to U.S. dollar borrowings partially offset by U.S. dollar cash investments. We have historically used interest rate derivative instruments to manage our earnings and cash flow exposure to changes in interest rates. We had interest rate derivative instruments outstanding in the contract amount of $1.000 billion as of December 31, 2018 and no interest rate derivative instruments outstanding as of December 31, 2017. As of December 31, 2018, $4.800 billion of our outstanding debt obligations was at fixed interest rates, representing approximately 68 percent of our total debt.

Certain of our non-designated forward currency contracts outstanding as of December 31, 2018, relate to hedging a portion of the purchase price of the proposed BTG Acquisition ($2.550 billion notional value as of December 31, 2018). During the first quarter of 2019, we entered into additional non-designated forward currency contracts, after which our combined notional value is £3.311 billion, which represents the full purchase price for the proposed BTG Acquisition.

See *Note D – Hedging Activities and Fair Value Measurements* to our consolidated financial statements contained in Item 8. Financial Statements and Supplementary Data of this Annual Report for further information regarding our derivative financial instruments.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Boston Scientific Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Boston Scientific Corporation (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and financial statement schedule listed in the Index at Item 15(a) (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 19, 2019 expressed an unqualified opinion thereon.

Adoption of ASU No. 2014-09

As discussed in Note A to the consolidated financial statements, the Company changed its method for recognizing revenue as a result of the adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), and the amendments in ASUs 2015-14, 2016-08, 2016-10 and 2016-12 effective January 1, 2018.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 1992.
Boston, Massachusetts
February 19, 2019

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

BOSTON SCIENTIFIC CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
(in millions, except per share data)	**2018**	**2017**	**2016**
Net sales	$ 9,823	$ 9,048	$ 8,386
Cost of products sold	2,813	2,593	2,424
Gross profit	7,011	6,455	5,962
Operating expenses:			
Selling, general and administrative expenses	3,569	3,294	3,099
Research and development expenses	1,113	997	920
Royalty expense	70	68	79
Amortization expense	599	565	545
Intangible asset impairment charges	35	4	11
Contingent consideration expense (benefit)	(21)	(80)	29
Restructuring charges (credits)	36	37	28
Litigation-related charges (credits)	103	285	804
	5,504	5,170	5,515
Operating income (loss)	1,506	1,285	447
Other income (expense):			
Interest expense	(241)	(229)	(233)
Other, net	156	(124)	(37)
Income (loss) before income taxes	1,422	933	177
Income tax (benefit) expense	(249)	828	(170)
Net income (loss)	**$ 1,671**	**$ 104**	**$ 347**
Net income (loss) per common share — basic	**$ 1.21**	**$ 0.08**	**$ 0.26**
Net income (loss) per common share — assuming dilution	**$ 1.19**	**$ 0.08**	**$ 0.25**

Weighted-average shares outstanding			
Basic	1,381.0	1,370.1	1,357.6
Assuming dilution	1,401.4	1,392.7	1,377.2

See notes to the consolidated financial statements.

BOSTON SCIENTIFIC CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Year Ended December 31,		
(in millions)	**2018**	**2017**	**2016**
Net income (loss)	$ 1,671	$ 104	$ 347
Other comprehensive income (loss), net of tax:			
Foreign currency translation adjustment	(21)	48	(25)
Net change in derivative financial instruments	110	(106)	(45)
Net change in available-for-sale securities	—	5	(6)
Net change in defined benefit pensions and other items	2	(6)	(11)
Total other comprehensive income (loss)	91	(59)	(87)
Total comprehensive income (loss)	**$ 1,761**	**$ 45**	**$ 260**

See notes to the consolidated financial statements.

BOSTON SCIENTIFIC CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

(in millions, except share and per share data)	As of December 31, 2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 146	$ 188
Trade accounts receivable, net	1,608	1,548
Inventories	1,166	1,078
Prepaid income taxes	161	66
Other current assets	921	942
Total current assets	4,003	3,822
Property, plant and equipment, net	1,782	1,697
Goodwill	7,911	6,998
Other intangible assets, net	6,372	5,837
Other long-term assets	932	688
TOTAL ASSETS	**$ 20,999**	**$ 19,042**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current debt obligations	$ 2,253	$ 1,801
Accounts payable	349	530
Accrued expenses	2,246	2,456
Other current liabilities	412	867
Total current liabilities	5,260	5,654
Long-term debt	4,803	3,815
Deferred income taxes	328	191
Other long-term liabilities	1,882	2,370
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value - authorized 50,000,000 shares, none issued and outstanding		
Common stock, $0.01 par value - authorized 2,000,000,000 shares; issued 1,632,148,030 shares as of December 31, 2018 and	16	16

1,621,062,898 shares as of December 31, 2017		
Treasury stock, at cost - 247,566,270 shares as of December 31, 2018 and December 31, 2017	(1,717)	(1,717)
Additional paid-in capital	17,346	17,161
Accumulated deficit	(6,953)	(8,390)
Accumulated other comprehensive income (loss), net of tax:		
Foreign currency translation adjustment	(53)	(32)
Unrealized gain (loss) on derivative financial instruments	111	1
Unrealized gain (loss) on available-for-sale securities	—	(1)
Unrealized costs associated with defined benefit pensions and other items	(25)	(27)
Total stockholders' equity	8,726	7,012
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 20,999**	**$ 19,042**

See notes to the consolidated financial statements.

BOSTON SCIENTIFIC CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in millions, except share data)	Common Stock Shares Issued	Common Stock Par Value	Treasury Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss), Net of Tax
Balance as of December 31, 2015	**1,594,213,786**	**$ 16**	**$ (1,717)**	**$ 16,860**	**$ (8,927)**	**$ 88**
Net income (loss)					347	
Changes in other comprehensive income (loss), net of tax:						
Foreign currency translation adjustment						(25)
Derivative financial instruments						(45)
Available-for-sale securities						(6)
Defined benefit pensions and other items						(11)
Impact of stock-based compensation plans, net of tax	15,457,031			153		
Rounding				1	(1)	
Balance as of December 31, 2016	**1,609,670,817**	**$ 16**	**$ (1,717)**	**$ 17,014**	**$ (8,581)**	**$ 1**
Net income (loss)					104	
Cumulative effect adjustment for ASU 2016-09					86	
Changes in other comprehensive income (loss), net of tax:						
Foreign currency translation adjustment						48
Derivative financial instruments						(106)
Available-for-sale securities						5
Defined benefit pensions and other items						(6)
Impact of stock-based compensation plans, net of tax	11,392,081			147		
Balance as of December 31, 2017	**1,621,062,898**	**$ 16**	**$ (1,717)**	**$ 17,161**	**$ (8,390)**	**$ (59)**
Net income (loss)					1,671	
Cumulative effect adjustment for ASU Adoptions[1]					(233)	
Changes in other comprehensive income (loss), net of tax:						
Foreign currency translation adjustment						(21)
Derivative financial instruments						110
Available-for-sale securities						—

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Defined benefit pensions and other items						2
Impact of stock-based compensation plans, net of tax	11,085,132			185		
Balance as of December 31, 2018	**1,632,148,030**	**$ 16**	**$ (1,717)**	**$ 17,346**	**$ (6,953)**	**$ 33**

(1) In 2018, we recorded a cumulative effect adjustment to Retained Earnings to reflect the adoption of ASU 2014-09, ASU 2016-16 and ASU 2016-01. Please refer to *Note A – Significant Accounting Policies* for additional details.

See notes to the consolidated financial statements.

BOSTON SCIENTIFIC CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in millions)	Year Ended December 31, 2018	2017	2016
Operating Activities			
Net income (loss)	$ 1,671	$ 104	$ 347
Adjustments to reconcile net income (loss) to cash provided by operating activities			
Depreciation and amortization	894	844	815
Deferred and prepaid income taxes	(87)	245	(305)
Stock-based compensation expense	140	127	116
Intangible asset impairment charges	35	4	11
Net loss (gain) on investments and notes receivable	(155)	92	21
Contingent consideration expense (benefit)	(21)	(80)	29
Payment of contingent consideration in excess of amount recognized at acquisition	(9)	(14)	(57)
Inventory step-up amortization	6	10	22
Other, net	(3)	27	(23)
Increase (decrease) in operating assets and liabilities, net of acquisitions:			
Trade accounts receivable	(110)	(30)	(216)
Inventories	(83)	(107)	40
Other assets	(172)	(20)	(43)
Accounts payable and accrued expenses	(631)	195	553
Other liabilities	(1,164)	28	(128)
Cash provided by (used for) operating activities	310	1,426	1,182
Investing Activities			
Purchases of property, plant and equipment	(316)	(319)	(376)
Proceeds on disposals of property, plant and equipment	14	—	29
Payments for acquisitions of businesses, net of cash acquired	(1,448)	(560)	(408)
Payments for investments and acquisitions of certain technologies	(172)	(131)	(132)
Cash provided by (used for) investing activities	(1,921)	(1,010)	(887)
Financing Activities			
Payments of contingent consideration previously established in purchase accounting	(19)	(33)	(65)
Proceeds from short-term borrowings, net of debt issuance costs	999	—	—
Net increase (decrease) in commercial paper	21	1,183	—
Proceeds from borrowings on credit facilities	569	2,156	630
Payments on borrowings from credit facilities	(569)	(2,216)	(570)

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Payments on long-term borrowings	(602)	(1,000)	(250)
Proceeds from long-term borrowings, net of debt issuance and extinguishment costs	987	—	—
Cash used to net share settle employee equity awards	(56)	(65)	(62)
Proceeds from issuances of shares of common stock	101	85	111
Cash provided by (used for) financing activities	1,432	110	(206)
Effect of foreign exchange rates on cash	(8)	4	(2)
Net increase (decrease) in cash, cash equivalents, restricted cash and restricted cash equivalents	(188)	530	87
Cash, cash equivalents, restricted cash and restricted cash equivalents at beginning of period	1,017	487	400
Cash, cash equivalents, restricted cash and restricted cash equivalents at end of period	**$ 829**	**$ 1,017**	**$ 487**
Supplemental Information			
Cash (received) paid for income taxes, net	$ 1,037	$ (42)	$ 94
Cash paid for interest	262	235	233
Fair value of contingent consideration recorded in purchase accounting	248	94	50

	As of December 31,		
Reconciliation to amounts within the consolidated balance sheets:	**2018**	**2017**	**2016**
Cash and cash equivalents	$ 146	$ 188	$ 196
Restricted cash and restricted cash equivalents included in *Other current assets*	655	803	269
Restricted cash equivalents included in *Other long-term assets*	27	26	22
Cash, cash equivalents, restricted cash and restricted cash equivalents at end of period	**$ 829**	**$ 1,017**	**$ 487**

See notes to the consolidated financial statements.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE A – SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

Our consolidated financial statements include the accounts of Boston Scientific Corporation and our wholly-owned subsidiaries, after the elimination of intercompany transactions. When used in this report, the terms "we," "us," "our" and "the Company" mean Boston Scientific Corporation and its divisions and subsidiaries. We assess the terms of our investment interests to determine if any of our investees meet the definition of a variable interest entity (VIE). For any VIEs, we perform an analysis to determine whether our variable interests give us a controlling financial interest in a VIE. The analysis identifies the primary beneficiary of a VIE as the enterprise that has both 1) the power to direct activities of a VIE that most significantly impact the entity's economic performance and 2) the obligation to absorb losses of the entity or the right to receive benefits from the entity. Based on our assessments under the applicable guidance, we did not have controlling financial interests in any VIEs and, therefore, did not consolidate any VIEs for 2018, 2017 and 2016.

Basis of Presentation

The accompanying consolidated financial statements and notes thereto have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) and with the instructions to Form 10-K and Regulation S-X.

Amounts reported in millions within this report are computed based on the amounts in thousands. As a result, the sum of the components reported in millions may not equal the total amount reported in millions due to rounding. Certain columns and rows within tables may not add due to the use of rounded numbers. Percentages presented are calculated from the underlying numbers in dollars. Balances in 2016 and 2015 balances were subject to rounding.

Revision of Reportable Segments

Effective January 1, 2018, following organizational changes to align the structure of our business with our focus on active implantable devices, we revised our reportable segments, in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 280, *Segment Reporting*. The revision reflects a reclassification of our Neuromodulation business from our Medical Surgical (MedSurg) segment to our newly created Rhythm and Neuro segment. We have revised prior year amounts to conform to the current year's presentation (as denoted with an asterisk (*) throughout). There was no revision to operating segments or reporting units as a result of the organizational change. See *Note C - Goodwill and Other Intangible Assets* and *Note N - Segment Reporting* for further details.

Subsequent Events

We evaluate events occurring after the date of our accompanying consolidated balance sheets for potential recognition or disclosure in our consolidated financial statements. We did not identify any material subsequent events requiring adjustment to our accompanying consolidated financial statements (recognized subsequent events). Those items requiring disclosure (unrecognized subsequent events) in the consolidated financial statements have been disclosed accordingly. Refer to *Note B – Acquisitions and Strategic Investments*, *Note D – Hedging Activities and Fair Value Measurements* and *Note J – Commitments and Contingencies* for further details.

Accounting Estimates

To prepare our consolidated financial statements in accordance with U.S. GAAP, management makes estimates and assumptions that may affect the reported amounts of our assets and liabilities, the disclosure of contingent liabilities as of the date of our consolidated financial statements and the reported amounts of our revenues and expenses during the reporting period. Our actual results may differ from these estimates. Refer to *Critical Accounting Estimates* included in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report for further discussion.

Cash, Cash Equivalents, Restricted Cash and Restricted Cash Equivalents

Cash and Cash Equivalents

We record *Cash and cash equivalents* in our consolidated balance sheets at cost, which approximates fair value. Our policy is to invest excess cash in short-term marketable securities earning a market rate of interest without assuming undue risk of loss of principal amounts invested and we limit our direct exposure to securities in any one industry or issuer. We consider to be cash equivalents all short-term marketable securities with remaining days to maturity of 90 days or less from the purchase date that can be readily converted to cash.

Restricted Cash and Restricted Cash Equivalents

Amounts included in restricted cash represent cash on hand required to be set aside by a contractual agreement related to receivable factoring arrangements and deferred compensation plans and are included in the *Other current assets* caption on our consolidated balance sheets. Generally, the restrictions related to the factoring arrangements lapse at the time we remit the customer payments collected by us as servicer of previously sold customer receivables to the purchaser. Restrictions for deferred compensation lapse when amounts are paid to the employee. Restricted cash equivalents primarily represent amounts paid into various qualified settlement funds related to our ongoing transvaginal surgical mesh litigation and current amounts related to our non-qualified pension plan and are included in the *Other current assets* caption on our consolidated balance sheets. The restrictions related to the various qualified settlement funds will lapse as we approve amounts payable to claimants, at which time we no longer have rights to a return of the amounts paid into the various qualified settlement funds. Restricted cash equivalents included in the *Other long-term assets* caption on our consolidated balance sheets are related to the long-term portion of our non-qualified pension plan and deferred compensation plans.

Concentrations of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash and cash equivalents, derivative financial instruments and accounts and notes receivable. Our investment policy limits exposure to concentrations of credit risk and changes in market conditions. Counterparties to financial instruments expose us to credit-related losses in the event of nonperformance. We transact our financial instruments with a diversified group of major financial institutions with investment grade credit ratings and actively monitor their credit ratings and our outstanding positions to limit our credit exposure. In the normal course, our payment terms with customers, including hospitals, healthcare agencies, clinics, doctors' offices and other private and governmental institutions, are typically 30 days in the U.S. but may be longer in international markets and generally do not require collateral. We record our Accounts receivable in our consolidated balance sheets at net realizable value. We perform ongoing credit evaluations of our customers and maintain allowances for potential credit losses, based on historical information and management's best estimates. We write-off amounts determined to be uncollectible against this reserve. Write-offs of uncollectible accounts receivable were immaterial in 2018, 2017 and 2016. We are not dependent on any single institution, and no single customer accounted for more than ten percent of our net sales in 2018, 2017 and 2016; however, large group purchasing organizations, hospital networks and other buying groups have become increasingly important to our business and represent a substantial portion of our U.S. net sales.

We closely monitor outstanding receivables for potential collection risks, including those that may arise from economic conditions, in both the U.S. and international economies. Our European sales to government-owned or supported customers in Southern Europe, specifically Greece, Italy, Spain and Portugal are subject to an increased number of days outstanding relative to other countries prior to payment. Historically, receivable balances with certain publicly-owned hospitals in these countries accumulated over a period of time and are then subsequently settled as large lump sum payments. While we believe our allowance for doubtful accounts in these countries is adequate as of December 31, 2018 and 2017, if significant changes were to occur in the payment practices of these European governments or if government funding becomes unavailable, we may not be able to collect on receivables due to us from these customers, and our write-offs of uncollectible accounts receivable may increase.

Revenue Recognition

ASC Update No. 2014-09

In May 2014, the FASB issued FASB ASC Topic 606, *Revenue from Contracts with Customers* (Topic 606), which was subsequently updated. We adopted the standard as of January 1, 2018, using the modified retrospective method. Under this method, we applied FASB ASC Topic 606 to contracts that were not complete as of January 1, 2018 and recognized the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings. Results for reporting periods beginning after

January 1, 2018 are presented in accordance with FASB ASC Topic 606. Prior period amounts are not adjusted and are reported in accordance with legacy GAAP requirements in FASB ASC Topic 605, *Revenue Recognition*.

Due to the adoption of FASB ASC Topic 606, we recorded a net reduction to retained earnings of $177 million on January 1, 2018, primarily related to the cost of providing non-contractual post-implant support to certain customers, which we historically deemed immaterial in the context of the arrangement. Upon the adoption of FASB ASC Topic 606, when we sell a device with an implied non-contractual post-implant support obligation, we forward accrue the cost of the service within *Selling, general and administrative expenses* and recognize it at the point in time the associated revenue is earned. We release the accrual over the related service period. These costs were previously expensed as incurred due to such service obligation being non-contractual.

The impact of adopting FASB ASC Topic 606 on our consolidated balance sheets resulted in an increase in *Other current liabilities* of $59 million and an increase in *Other long-term liabilities* of $205 million as of December 31, 2018, as a result of accruing for our post-implant support obligation. We also recorded deferred tax assets primarily related to post-implant support, resulting in an increase in *Other long-term assets* of $12 million and a reduction in *Deferred income taxes* of $41 million as of December 31, 2018. The remaining impact of adopting FASB ASC Topic 606 was not material to our financial position or results of operations.

We sell our products primarily through a direct sales force. In certain international markets, we sell our products through independent distributors. We consider revenue to be earned when all of the following criteria are met:

- We have a contract with a customer that creates enforceable rights and obligations,
- Promised products or services are identified,
- The transaction price, or the amount we expect to receive, is determinable and
- We have transferred control of the promised items to the customer.

Transfer of control is evidenced upon passage of title and risk of loss to the customer unless we are required to provide additional services. We treat shipping and handling costs performed after a customer obtains control of the good as a fulfillment cost and record these costs as a selling expense when incurred. We recognize revenue from consignment arrangements based on product usage, or implant, which indicates that the sale is complete. We recognize a receivable at the point in time we have an unconditional right to payment. Payment terms are typically 30 days in the U.S. but may be longer in international markets.

Deferred Revenue

We record a contract liability, or deferred revenue, when we have an obligation to provide a product or service to the customer and payment is received or due in advance of our performance. When we sell a device with a future service obligation, we defer revenue on the unfulfilled performance obligation and recognize this revenue over the related service period. Many of our Cardiac Rhythm Management (CRM) product offerings combine the sale of a device with our LATITUDE™ Patient Management System, which represents a future service obligation. Generally, we do not have observable evidence of the standalone selling price related to our future service obligations; therefore, we estimate the selling price using an expected cost plus a margin approach. We allocate the transaction price using the relative standalone selling price method. The use of alternative estimates could result in a different amount of revenue deferral.

Contract liabilities are classified within *Other current liabilities* and *Other long-term liabilities* on our accompanying consolidated balance sheets. Our contractual liabilities are primarily composed of deferred revenue related to the LATITUDE Patient Management System. Revenue is recognized over the average service period which is based on device and patient longevity. We have elected not to disclose the transaction price allocated to unsatisfied performance obligations when the original expected contract duration is one year or less. In addition, we have not identified material unfulfilled performance obligations for which revenue is not currently deferred.

Variable Consideration

We generally allow our customers to return defective, damaged and, in certain cases, expired products for credit. We base our estimate for sales returns upon historical trends and record the amount as a reduction to revenue when we sell the initial product. In addition, we may allow customers to return previously purchased products for next-generation

product offerings. For these transactions, we defer recognition of revenue on the sale of the earlier generation product based upon an estimate of the amount of product to be returned when the next-generation products are shipped to the customer. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls and variation in product utilization all affect our estimates related to sales returns and could cause actual returns to differ from these estimates.

We also offer sales rebates and discounts to certain customers. We treat sales rebates and discounts as a reduction of revenue and classify the corresponding liability as current. We estimate rebates for products where there is sufficient historical information available to predict the volume of expected future rebates. If we are unable to reasonably estimate the expected rebates, we record a liability for the maximum rebate percentage offered. We have entered certain agreements with group purchasing organizations to sell our products to participating hospitals at negotiated prices. We recognize revenue from these agreements following the same revenue recognition criteria discussed above.

Capitalized Contract Costs

We capitalize commission fees related to contracts with customers when the associated revenue is expected to be earned over a period that exceeds one year. Deferred commissions are primarily related to the sale of devices enabled with our LATITUDE™ Patient Management System. We have elected to expense commission costs when incurred for contracts with an expected duration of one year or less. Capitalized commission fees are amortized over the period the associated products or services are transferred. Similarly, we capitalize certain recoverable costs related to the delivery of the LATITUDE Remote Monitoring Service. These fulfillment costs are amortized over the average service period. Our total capitalized contract costs are immaterial to our consolidated financial statements.

Post Implant Services

We provide non-contractual services to customers to ensure the safe and effective use of certain implanted devices. Since our modified retrospective adoption of FASB ASC Topic 606 on January 1, 2018, because the revenue related to the immaterial services is recognized before they are delivered, we forward accrue the costs to provide these services at the time the devices are sold. We record these costs to *Selling, general and administrative expenses*. We estimate the amount of time spent by our representatives performing these services and their compensation throughout the device life to determine the service cost. Changes to our business practice or the use of alternative estimates could result in a different amount of accrued cost.

Warranty Obligations

We offer warranties on certain of our product offerings. The majority of our warranty liability relates to implantable devices offered by our CRM business, which include defibrillator and pacemaker systems. Our CRM products come with a standard limited warranty covering the replacement of these devices. We offer a full warranty for a portion of the period post-implant and a partial warranty for a period of time thereafter. We estimate the costs that we may incur under our warranty programs based on the number of units sold, historical and anticipated rates of warranty claims and cost per claim and record a liability equal to these estimated costs as cost of products sold at the time the product sale occurs. We assess the adequacy of our recorded warranty liabilities on a quarterly basis and adjust these amounts as necessary. Aggregate year over year changes in our product warranty accrual during 2018, 2017 and 2016 were immaterial.

Inventories

We state inventories at the lower of first-in, first-out cost or net realizable value. We base our provisions for excess, expired and obsolete inventory primarily on our estimates of forecasted net sales. A significant change in the timing or level of demand for our products as compared to forecasted amounts may result in recording additional provisions for excess, expired and obsolete inventory in the future. Further, the industry in which we participate is characterized by rapid product development and frequent new product introductions. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls and variation in product utilization all affect our estimates related to excess, expired and obsolete inventory. Approximately 40 percent of our finished goods inventory as of both December 31, 2018 and December 31, 2017 was at customer locations pursuant to consignment arrangements or held by sales representatives.

Property, Plant and Equipment

We state property, plant, equipment and leasehold improvements at historical cost. We charge expenditures for maintenance and repairs to expense and capitalize additions and improvements that extend the life of the underlying asset. We provide for depreciation using the straight-line method at rates that approximate the estimated useful lives of the assets. We depreciate buildings over a maximum life of 40 years; building improvements over the remaining useful life of the building structure; equipment, furniture and fixtures over a three to seven year life; and leasehold improvements over the shorter of the useful life of the improvement or the term of the related lease.

Valuation of Business Combinations

We allocate the amounts we pay for each acquisition to the assets we acquire and liabilities we assume based on their fair values at the date of acquisition, including identifiable intangible assets and in-process research and development (IPR&D), which either arise from a contractual or legal right or are separable from goodwill. We base the fair value of identifiable intangible assets acquired in a business combination, including IPR&D, on detailed valuations that use information and assumptions provided by management, which consider management's best estimates of inputs and assumptions that a market participant would use. We allocate to goodwill any excess purchase price over the fair value of the net tangible and identifiable intangible assets acquired. Transaction costs associated with these acquisitions are expensed as incurred through *Selling, general and administrative expenses*.

In those circumstances where an acquisition involves a contingent consideration arrangement, we recognize a liability equal to the fair value of the contingent payments we expect to make as of the acquisition date. We re-measure this liability each reporting period and record changes in the fair value through *Contingent consideration expense (benefit)* on our consolidated statements of operations. Increases or decreases in the fair value of the contingent consideration liability can result from changes in discount rates, periods, timing and amount of projected revenue or timing or likelihood of achieving regulatory, revenue or commercialization-based milestones. Payment of additional consideration is generally contingent on the acquired company reaching certain performance milestones after the acquisition date, including attaining specified revenue levels, achieving product development targets and/or obtaining regulatory approvals for products in development at the date of the acquisition.

Indefinite-lived Intangibles, including IPR&D

Our indefinite-lived intangible assets, which are not subject to amortization, include acquired balloon and other technology, which is foundational to our ongoing operations within the Cardiovascular market and other markets within interventional medicine and IPR&D intangible assets acquired in a business combination. Our IPR&D represents intangible assets acquired in a business combination that are used in research and development activities but have not yet reached technological feasibility, regardless of whether they have alternative future use. The primary basis for determining the technological feasibility or completion of these projects is obtaining regulatory approval to market the underlying products in an applicable geographic region. We classify IPR&D acquired in a business combination as an indefinite-lived intangible asset until the completion or abandonment of the associated research and development efforts. Upon completion of the associated research and development efforts, we will determine the useful life of the technology and begin amortizing the assets to reflect their use over their remaining lives. Upon permanent abandonment, we write-off the remaining carrying amount of the associated IPR&D intangible asset.

We test our indefinite-lived intangible assets at least annually during the third quarter for impairment and reassess their classification as indefinite-lived assets. In addition, we review our indefinite-lived intangible assets for classification and impairment more frequently if changes in circumstances or impairment indicators exist. We assess qualitative factors to determine whether the existence of events and circumstances indicate that it is more likely than not that our indefinite-lived intangible assets are impaired. If we conclude that it is more likely than not that the asset is impaired, we then determine the fair value of the intangible asset and perform the quantitative impairment test by comparing the fair value with the carrying value in accordance with FASB ASC Topic 350, *Intangibles - Goodwill and Other*. If the carrying value exceeds the fair value of the indefinite-lived intangible asset, we write the carrying value down to the fair value.

We use the income approach to determine the fair values of our IPR&D. We base our revenue assumptions on estimates of relevant market sizes, expected market growth rates, expected trends in technology and expected levels of market share. In arriving at the value of the in-process projects, we consider, among other factors, the in-process projects' stage of completion, the complexity of the work completed as of the acquisition date, the costs already incurred, the projected costs to complete, the contribution of other acquired assets, the expected regulatory path and introduction dates by region and the estimated useful life of the technology. See *Note C - Goodwill and Other Intangible Assets* for more information related to indefinite-lived intangibles, including IPR&D.

For asset purchases outside of business combinations, we expense any purchased research and development assets as of the acquisition date.

Amortization and Impairment of Intangible Assets

We record definite-lived intangible assets at historical cost and amortize them over their estimated useful lives. We use a straight-line method of amortization, unless a method that better reflects the pattern in which the economic benefits of the intangible asset are consumed or otherwise used up can be reliably determined. The approximate useful lives for amortization of our intangible assets are as follows: patents and licenses, two to 20 years; amortizable technology-related and customer relationships, five to 25 years; other intangible assets, various.

We review intangible assets subject to amortization quarterly to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life. Conditions that may indicate impairment include, but are not limited to, a significant adverse change in legal factors or business climate that could affect the value of an asset, a product recall or an adverse action or assessment by a regulator. If we determine it is more likely than not that the asset is impaired based on our qualitative assessment of impairment indicators, we test the intangible asset for recoverability. For purposes of the recoverability test, we group our amortizable intangible assets with other assets and liabilities at the lowest level of identifiable cash flows if the intangible asset does not generate cash flows independent of other assets and liabilities. If the carrying value of the intangible asset or asset group exceeds the undiscounted cash flows expected to result from the use and eventual disposition of the intangible asset or asset group, we will write the carrying value down to fair value in the period impairment is identified.

We calculate fair value of our intangible assets as the present value of estimated future cash flows we expect to generate from the asset. In determining our estimated future cash flows associated with our intangible assets, we use estimates and assumptions about future revenue contributions, cost structures and remaining useful lives of the asset or asset group. See *Note C - Goodwill and Other Intangible Assets* for more information related to impairments of intangible assets.

For patents developed internally, we capitalize costs incurred to obtain patents, including attorney fees, registration fees, consulting fees and other expenditures directly related to securing the patent.

Goodwill Valuation

We allocate any excess purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination to goodwill. We test our goodwill balances during the second quarter of each year for impairment or more frequently if indicators are present or changes in circumstances suggest that impairment may exist. We assess goodwill for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment, referred to as a component. For our 2018, 2017 and 2016 annual impairment assessment, we identified seven reporting units: Interventional Cardiology, Peripheral Interventions, Cardiac Rhythm Management, Electrophysiology, Endoscopy, Urology and Pelvic Health and Neuromodulation. We aggregated the Cardiac Rhythm Management and Electrophysiology reporting units, components of the Rhythm Management operating segment, based on the criteria prescribed in FASB ASC Topic 350. These reporting units were aggregated due to a reorganization that commenced in 2015 that resulted in integrated leadership, shared resources and consolidation of certain sites in 2016.

In performing the goodwill impairment assessments for 2018, 2017 and 2016, we utilized both the optional qualitative assessment and the quantitative approach prescribed under FASB ASC Topic 350. The qualitative assessment was used for testing certain reporting units where fair value has historically exceeded carrying value by greater than 100 percent. All other reporting units were tested using the quantitative approach described below. The qualitative assessment requires an evaluation of whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount based on an assessment of relevant events including macroeconomic factors, industry and market conditions, cost factors, overall financial performance and other entity-specific factors. After assessing the totality of events, if it is determined that it is more likely than not that the fair value of the reporting unit exceeds its carrying value, no further steps are required. If it is determined that impairment is more likely than not, then we perform the quantitative impairment test. In 2018, we performed a qualitative assessment for our Urology and Pelvic Health and Neuromodulation reporting units since their fair values have exceeded carrying value by greater than 100 percent. The remaining reporting units were quantitatively tested for impairment. For all reporting units tested using the optional qualitative assessment, no further steps were required, and we concluded such reporting units were not impaired. For all reporting units tested using the quantitative approach, we concluded that the fair value of each reporting unit exceeded its carrying value.

When allocating goodwill from business combinations to our reporting units, we assign goodwill to the reporting units that we expect to benefit from the respective business combination at the time of acquisition. In addition, for purposes of performing our goodwill impairment tests, assets and liabilities, including corporate assets, which relate to a reporting unit's operations, and would be considered in determining its fair value, are allocated to the individual reporting units. We allocate assets and liabilities not directly related to a specific reporting unit, but from which the reporting unit benefits, based primarily on the respective revenue contribution of each reporting unit.

For our 2018, 2017 and 2016 annual impairment assessments, for those reporting units for which a quantitative test was performed, we used only the income approach, specifically the Discounted Cash Flow method, to derive the fair value of each of our reporting units in preparing our goodwill impairment assessments. We selected this method as being the most meaningful in preparing our goodwill assessments because we believe the income approach most appropriately measures our income producing assets. We have considered

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

using the market approach and cost approach but concluded they are not appropriate in valuing our reporting units given the lack of relevant market comparisons available for application of the market approach and the inability to replicate

the value of the specific technology-based assets within our reporting units for application of the cost approach. Therefore, we believe that the income approach represents the most appropriate valuation technique for which sufficient data are available to determine the fair value of our reporting units.

In applying the income approach to our accounting for goodwill, we make assumptions about the amount and timing of future expected cash flows, terminal value growth rates and appropriate discount rates. The amount and timing of future cash flows within our Discounted Cash Flow analysis is based on our most recent operational budgets, long range strategic plans and other estimates. The terminal value growth rate reflects our best estimates for stable, perpetual growth of our reporting units. We use estimates of market-participant risk-adjusted weighted average cost of capital as a basis for determining the discount rates to apply to our reporting units' future expected cash flows.

Refer to *Note C - Goodwill and Other Intangible Assets* to our consolidated financial statements for additional details related to our goodwill balances.

Investments in Publicly Traded and Privately Held Entities

ASC Update No. 2016-01

In January 2016, the FASB issued ASC Update No. 2016-01, *Financial Instruments - Overall* (Subtopic 825-10)*: Recognition and Measurement of Financial Assets and Financial Liabilities.* The purpose of Update No. 2016-01 is to improve financial reporting for financial instruments by reducing the number of items recorded to other comprehensive income. We adopted Update No. 2016-01 in the first quarter of 2018, using both the modified retrospective and prospective methods. For publicly-held securities, we used the modified retrospective approach. Unrealized gains and losses previously recorded to *Other comprehensive income (loss)* were reclassified to retained earnings, and all future fair value changes will be recorded to *Net income (loss)*. For privately-held securities that we do not have the ability to exercise significant influence over the investee, we elected the measurement alternative approach for our existing investments, which is applied prospectively upon adoption. This approach requires entities to measure their investments at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. The adoption of the standard did not have a material impact on our financial position or results of operations. The actual impact to future periods resulting from fair value changes of our equity investments is difficult to predict as it will depend on their future performance.

In 2017 and 2016, we accounted for our publicly traded investments as available-for-sale securities based on the quoted market price at the end of the reporting period. Unrealized holding gains or losses during the period, net of tax, were recorded to *Accumulated other comprehensive income (loss), net of tax*. We computed realized gains and losses on sales of available-for-sale securities at fair value, adjusted for any other-than-temporary declines in fair value. We accounted for investments in private entities in which we have less than a 20 percent ownership interest under the cost method of accounting if we do not have the ability to exercise significant influence over the investee in accordance with FASB ASC Topic 325*, Investments - Other*.

We account for investments in entities over which we have the ability to exercise significant influence under the equity method if we hold 50 percent or less of the voting stock and the entity is not a VIE in which we are the primary beneficiary in accordance with FASB ASC Topic 323, *Investments - Equity Method and Joint Ventures*. We record these investments initially at cost and adjust the carrying amount to reflect our share of the earnings or losses of the investee, including all adjustments similar to those made in preparing consolidated financial statements. Lastly, we have notes receivable from certain companies that we account for in accordance with FASB ASC Topic 320*, Investments - Debt and Equity Securities*. Refer to *Note B – Acquisitions and Strategic Investments* for additional details on our investment balances.

Each reporting period, we evaluate our investments to determine if there are any events or circumstances that are likely to have a significant adverse effect on the fair value of the investment. Examples of such impairment indicators include, but are not limited to, a significant deterioration in earnings performance, recent financing rounds at reduced valuations, a significant adverse change in the regulatory, economic or technological environment of an investee or a significant doubt about an investee's ability to continue as a going concern. If we identify an impairment indicator, we will estimate the fair value of the investment and compare it to its carrying value. Our estimation of fair value considers financial information related to the investee available to us, including valuations based on recent third-party equity investments in the investee. If the fair value of the investment is less than its carrying value, the investment is impaired and we recognize an impairment loss equal to the difference between an investment's carrying value and its fair value if accounted for under measurement alternative. For our equity method investments, an impairment loss is recorded if we determine the impairment is other-than-temporary. We deem an impairment to be other-than-temporary unless available evidence indicates that the valuation is more likely than not to recover up to the carrying value of the investment in a

reasonable period of time, and we have both the ability and intent to hold the investment for a sufficient period of time needed to recover the value. For other-than-temporary impairments, we recognize an impairment loss equal to the difference between an

investment's carrying value and its fair value. Impairment losses on our investments are included in *Other, net* in our consolidated statements of operations.

Income Taxes

ASC Update No. 2016-16

In October 2016, the FASB issued ASC Update No. 2016-16, *Income Taxes* (Topic 740): *Intra-Entity Transfers of Assets Other Than Inventory*. The purpose of Update No. 2016-16 is to allow an entity to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs, as opposed to waiting until the asset is sold to a third party, or impaired. Update No. 2016-16 was effective for annual periods beginning after December 15, 2017, including interim periods within those annual periods. We adopted Update No. 2016-16 prospectively in the first quarter of 2018 and recognized a net reduction to opening retained earnings of $55 million for income tax consequences not previously recognized for intra-entity transfers of assets other than inventories. All future income tax consequences of intra-entity transfers of assets other than inventories will be recognized through *Income tax expense (benefit)*.

We utilize the asset and liability method of accounting for income taxes. Under this method, we determine deferred tax assets and liabilities based on differences between the financial reporting and tax bases of our assets and liabilities. We measure deferred tax assets and liabilities using the enacted tax rates and laws that will be in effect when we expect the differences to reverse. We reduce our deferred tax assets by a valuation allowance if, based upon the weight of available evidence, it is more likely than not that we will not realize some portion or all of the deferred tax assets. We consider relevant evidence, both positive and negative, to determine the need for a valuation allowance. Information evaluated includes our financial position and results of operations for the current and preceding years, the availability of deferred tax liabilities and tax carrybacks, as well as estimates of the impact of future taxable income and available prudent and feasible tax-planning strategies. We recognize interest and penalties related to income taxes as a component of income tax expense. As part of the Tax Cut and Jobs Act of 2017 (TCJA), we are subject to a territorial tax system in which we are required to make an accounting policy in providing for tax on Global Intangible Low Taxed Income (GILTI) earned by certain foreign subsidiaries. We have elected to treat the impact of GILTI as a period cost and will be reported as a part of continuing operations. See *Note I - Income Taxes* for further information and discussion of our income tax provision and balances including a discussion of the impacts of the TCJA.

Legal and Product Liability Costs

In the normal course of business, we are involved in various legal and regulatory proceedings, including intellectual property, breach of contract, securities litigation and product liability suits. In some cases, the claimants seek damages, as well as other relief, which, if granted, could require significant expenditures or impact our ability to sell our products. We are also the subject of certain governmental investigations, which could result in substantial fines, penalties and administrative remedies. We maintain an insurance policy providing limited coverage against securities claims, and we are substantially self-insured with respect to product liability claims and fully self-insured with respect to intellectual property infringement claims. We accrue anticipated costs of settlement, damages, losses for product liability claims and, under certain conditions, costs of defense, based on historical experience or to the extent specific losses are probable and estimable. Otherwise, we expense these costs as incurred. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue our best estimate of the minimum amount of the range. We analyze litigation settlements to identify each element of the arrangement. We allocate arrangement consideration to patent licenses received based on estimates of fair value and capitalize these amounts as assets if the license will provide an ongoing future benefit. We record certain legal and product liability charges, credits and costs of defense, which we consider to be unusual or infrequent and significant as *Litigation-related charges (credits)* in our consolidated statements of operations; all other legal and product liability charges, credits and costs are recorded within *Selling, general and administrative expenses*. See *Note J – Commitments and Contingencies* for discussion of our individual material legal proceedings.

Costs Associated with Exit Activities

We record employee termination costs in accordance with FASB ASC Topic 712, *Compensation - Nonretirement and Postemployment Benefits*, if we pay the benefits as part of an ongoing benefit arrangement, which includes benefits provided as part of our established severance policies or that we provide in accordance with international statutory requirements. We accrue employee termination costs associated with an ongoing benefit arrangement if the obligation is attributable to prior services rendered, the rights to the benefits have vested, the payment is probable and we can reasonably estimate the liability. We account for employee termination benefits that represent a one-time benefit in accordance with FASB ASC Topic 420, *Exit or Disposal Cost Obligations*. We record such costs into expense over the employee's future service period, if any.

Other costs associated with exit activities may include contract termination costs, including costs related to consultant fees and contract cancellations. The costs are expensed in accordance with FASB ASC Topic 420 and FASB ASC Topic 360, *Property, Plant and Equipment* and are included in *Restructuring charges (credits)* in our consolidated statements of operations. Additionally, costs directly related to our active restructuring initiatives, including program management costs, accelerated depreciation, fixed asset write-offs and costs to transfer product lines among facilities are included within *Costs of products sold* and *Selling, general and administrative expenses* in our consolidated statements of operations. See *Note G – Restructuring-related Activities* for further information and discussion of our restructuring plans.

Translation of Foreign Currency

We translate all assets and liabilities of foreign subsidiaries from the functional currency, which is generally the local currency, into U.S. dollars using the year-end exchange rate and translate revenues and expenses at the average exchange rates in effect during the year. We show the net effect of these translation adjustments in our consolidated financial statements as a component of *Accumulated other comprehensive income (loss), net of tax*. For any significant foreign subsidiaries located in highly inflationary economies, we would re-measure their financial statements as if the functional currency were the U.S. dollar. We recorded immaterial highly inflationary economy translation adjustments in 2018, 2017 or 2016.

Foreign currency transaction gains and losses are included in *Other, net* in our consolidated statements of operations, net of losses and gains from any related derivative financial instruments.

Financial Instruments

ASC Update No. 2017-12

In August 2017, the FASB issued ASC Update No. 2017-12, *Derivatives and Hedging* (Topic 815)*: Targeted Improvements to Accounting for Hedging Activities*. The purpose of Update No. 2017-12 is to simplify the application of hedge accounting and better align financial reporting of hedging relationships with risk management objectives. Update No. 2017-12 was effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods. We early adopted Update No. 2017-12 in the first quarter of 2018. The adoption of the standard had no impact on our financial position or results of operations.

We recognize all derivative financial instruments in our consolidated financial statements at fair value in accordance with FASB ASC Topic 815, *Derivatives and Hedging*, and we present assets and liabilities associated with our derivative financial instruments on a gross basis in our financial statements. In accordance with FASB ASC Topic 815, for those derivative instruments that are designated and qualify as hedging instruments, the hedging instrument must be designated, based upon the exposure being hedged, as a fair value hedge, cash flow hedge, or a hedge of a net investment in a foreign operation. The accounting for changes in the fair value of a derivative instrument depends on whether it qualifies for, and has been designated as part of a hedging relationship, as well as on the type of hedging relationship. Our derivative instruments do not subject our earnings to material risk, as gains and losses on these derivatives generally offset gains and losses on the item being hedged. We do not enter into derivative transactions for speculative purposes, and we do not have any non-derivative instruments that are designated as hedging instruments pursuant to FASB ASC Topic 815. Refer to *Note D – Hedging Activities and Fair Value Measurements* for more information on our derivative instruments.

Shipping and Handling Costs

We generally do not bill customers for shipping and handling of our products. We treat shipping and handling costs incurred after a customer obtains control of the good as a fulfillment cost and record in *Selling, general and administrative expenses* in our consolidated statements of operations. Shipping and handling costs were $124 million in 2018, $110 million in 2017 and $101 million in 2016.

Research and Development

We expense research and development costs, including new product development programs, regulatory compliance and clinical research as incurred. Refer to *Indefinite-lived Intangibles, including In-Process Research and Development* above for our policy regarding IPR&D acquired in connection with our business combinations and asset purchases.

Net Income (Loss) per Common Share

We base *Net income (loss) per common share* upon the weighted-average number of common shares and common stock equivalents outstanding during each year. Potential common stock equivalents are determined using the treasury stock method. We exclude stock options and stock awards whose effect would be anti-dilutive from the calculation.

NOTE B – ACQUISITIONS AND STRATEGIC INVESTMENTS

Our consolidated financial statements include the operating results for each acquired entity from its respective date of acquisition. We do not present pro forma financial information for these acquisitions given their results are not material to our consolidated financial statements. Transaction costs associated with these acquisitions were expensed as incurred and are not material for 2018, 2017 and 2016.

Proposed BTG Acquisition

On November 20, 2018, our board of directors and the board of directors of our wholly owned indirect subsidiary, Bravo Bidco Limited (Bidco), and BTG plc (BTG), a public company organized under the laws of England and Wales, issued an announcement (the Rule 2.7 Announcement) under Rule 2.7 of the United Kingdom City Code on Takeovers and Mergers, disclosing the terms of a recommended cash offer to be made by Bidco for the entire issued and to be issued ordinary share capital of BTG (the proposed BTG Acquisition). On January 24, 2019, Bidco made such offer on the terms and subject to the conditions of the scheme document published on the same date. In connection with the proposed BTG Acquisition, (i) we entered into a co-operation agreement with Bidco and BTG (the Co-operation Agreement), (ii) certain shareholders and each BTG director owning shares of BTG delivered deeds of irrevocable undertakings to Bidco and (iii) we entered into a bridge credit agreement (the Bridge Facility). Refer to *Note E – Borrowings and Credit Arrangements* for further details of the Bridge Facility. On February 14, 2019, each of the Company and BTG received a request for additional information and documentary material from the United States Federal Trade Commission in connection with the proposed BTG Acquisition.

Under the terms of the proposed BTG Acquisition, BTG shareholders will receive 840 pence in cash for each BTG share, which values BTG's existing issued and to be issued ordinary share capital at approximately £3.311 billion (or approximately $4.225 billion based on the exchange rate of U.S. $1.28: £1.00 on December 31, 2018). We intend to implement the proposed BTG Acquisition by way of a court-sanctioned scheme of arrangement (Scheme) under Part 26 of the United Kingdom Companies Act 2006, as amended (the Companies Act).

The proposed BTG Acquisition will be subject to conditions and certain further terms, including (i) the approval of the Scheme by a majority in number of BTG shareholders also representing not less than 75 percent in value of the BTG shares, in each case, present, entitled to vote and voting, (ii) the sanction of the Scheme by the High Court of Justice in England and Wales, (iii) the Scheme becoming effective no later than August 20, 2019 and (iv) the receipt of regulatory approvals. The conditions to the proposed BTG Acquisition are set out in full in the Rule 2.7 Announcement. Subject to the satisfaction or waiver of all relevant conditions, we expect the proposed BTG Acquisition to be effective in the first half of 2019.

We are entitled to implement the proposed BTG Acquisition by way of a takeover offer (as defined in Part 28 of the Companies Act) in certain circumstances, subject to the terms of the Co-operation Agreement and the consent of the Panel on Takeovers and Mergers in the United Kingdom.

Pursuant to the Co-operation Agreement, the Company and Bidco have undertaken to use commercially reasonable efforts to secure the required regulatory clearances in respect of the proposed BTG Acquisition as soon as reasonably practicable, to provide each other with such information and assistance as may reasonably be required for the purpose of making any filing, notification or submission to relevant antitrust and regulatory authorities, and Bidco has agreed to provide BTG with information required for the preparation of Scheme documentation. The Co-operation Agreement addresses certain other matters, as set forth therein.

Invesco Asset Management Limited subsequently sold certain BTG shares, subject to its irrevocable undertaking, to certain funds managed by Pentwater Capital Management Europe LLP (together, the Pentwater Funds) and Woodford Investment Management Limited sold all of the BTG shares subject to its irrevocable undertaking to Arrowgrass Master Fund Limited and Anavio Capital Master Fund Limited and funds managed, variously, by Anavio Capital Partners LLP, Sand Grove Capital Management LLP, Tavira Securities and Melquart Asset Management (UK) Ltd. (all together with the Pentwater Funds, the New Shareholders). These BTG shares remain subject to deeds of irrevocable undertakings

under which each New Shareholder is committed, among other things, to vote its BTG shares in favor of the Scheme and against any proposal that would impede or frustrate the completion of the proposed BTG Acquisition.

The Shareholder Undertakings and the Director Undertakings will remain in effect if the Company and Bidco elect to effect the proposed BTG Acquisition by way of a takeover offer and will cease to be binding in certain circumstances.

BTG develops and commercializes products used in minimally-invasive procedures targeting cancer and vascular diseases, as well as acute care pharmaceuticals.

2019 Acquisitions

Millipede, Inc.

On January 29, 2019, we announced the closing of our acquisition of Millipede, Inc. (Millipede), a privately-held company that has developed the IRIS Transcatheter Annuloplasty Ring System for the treatment of severe mitral regurgitation. We have been an investor in Millipede since the first quarter of 2018 as part of an investment and acquisition option agreement, whereby we purchased a portion of the outstanding shares of Millipede along with newly issued shares of the company for an upfront cash payment of $90 million. In the fourth quarter of 2018, upon the recent successful completion of a first-in-human clinical study, we exercised our option to acquire the remaining shares of Millipede. We held an interest of approximately 20 percent immediately prior to the acquisition date. The transaction price for the remaining stake consists of an upfront cash payment of $325 million and up to an additional $125 million payment upon achievement of a commercial milestone. Millipede will be part of our Interventional Cardiology business. Our initial accounting for Millipede will be completed in the first quarter of 2019, and as such, the purchase price allocation in the aggregated disclosures below excludes Millipede.

2018 Acquisitions

Augmenix, Inc.

On October 16, 2018, we announced the closing of our acquisition of Augmenix, Inc. (Augmenix), a privately-held company that developed and commercialized the SpaceOAR™ Hydrogel System to help reduce common and debilitating side effects that men may experience after receiving radiotherapy to treat prostate cancer. The transaction price consists of an upfront cash payment of $500 million and up to $100 million in payments contingent upon revenue-based milestones. Augmenix is part of our Urology and Pelvic Health business.

Claret Medical, Inc.

On August 2, 2018, we announced the closing of our acquisition of Claret Medical, Inc. (Claret), a privately-held company that has developed and commercialized the Sentinel™ Cerebral Embolic Protection System. The device is used to protect the brain during certain interventional procedures, predominately in patients undergoing transcatheter aortic valve replacement (TAVR). The transaction price consists of an upfront cash payment of $220 million and an additional $50 million payment for reaching a reimbursement-based milestone that was achieved in the third quarter. Claret is part of our Interventional Cardiology business.

Cryterion Medical, Inc.

On July 5, 2018, we announced the closing of our acquisition of Cryterion Medical, Inc. (Cryterion), a privately-held company developing a single-shot cryoablation platform for the treatment of atrial fibrillation. We have been an investor in Cryterion since 2016 and held an interest of approximately 35 percent immediately prior to the acquisition date. The transaction price to acquire the remaining stake consists of an upfront cash payment of $202 million. Cryterion is part of our Electrophysiology business.

NxThera, Inc.

On April 30, 2018, we announced the closing of our acquisition of NxThera, Inc. (NxThera), a privately-held company that developed the Rezūm™ System, a minimally invasive therapy in a growing category of treatment options for patients with benign prostatic hyperplasia (BPH). We held a minority interest immediately prior to the acquisition date. The

transaction price to acquire the remaining stake consists of an upfront cash payment of approximately $240 million and up to approximately $85 million in commercial-based milestones. NxThera is part of our Urology and Pelvic Health business.

nVision Medical Corporation

On April 16, 2018, we announced the closing of our acquisition of nVision Medical Corporation (nVision), a privately-held company focused on women's health. nVision developed the first and only device cleared by the U.S. Food and Drug Administration (FDA) to collect cells from the fallopian tubes, offering a potential platform for earlier diagnosis of ovarian cancer. The transaction price consists of an upfront cash payment of $150 million and up to approximately $125 million in payments contingent upon clinical and commercial-based milestones. nVision is part of our Urology and Pelvic Health business.

In addition, we completed other individually immaterial acquisitions in 2018 for total consideration of $158 million in cash at closing plus aggregate contingent consideration of up to $62 million.

We recorded gains of $184 million in 2018 within *Other, net* on our consolidated statements of operations based on the difference between the book values and the fair values of our previously-held investments immediately prior to the acquisition dates, which aggregate to $251 million. We re-measured the fair value of each previously-held investment based on the implied enterprise value and allocation of purchase price consideration according to priority of equity interests.

Purchase Price Allocation

We accounted for these acquisitions as business combinations, and in accordance with FASB ASC Topic 805, *Business Combinations*, we recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition dates. The components of the aggregate preliminary purchase prices are as follows for our 2018 acquisitions as of December 31, 2018:

(in millions)		
Payments for acquisitions, net of cash acquired	$	1,449
Fair value of contingent consideration		248
Fair value of prior interests		251
	$	**1,948**

The following summarizes the preliminary purchase price allocations for our 2018 acquisitions as of December 31, 2018:

(in millions)		
Goodwill	$	942
Amortizable intangible assets		938
IPR&D		213
Other assets acquired		38
Liabilities assumed		(19)
Net deferred tax liabilities		(164)
	$	**1,948**

We allocated a portion of the preliminary purchase prices to specific intangible asset categories as follows:

	Amount Assigned *(in millions)*	**Amortization Period** *(in years)*	**Risk-Adjusted Discount Rates used in Purchase Price Allocation**

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Amortizable intangible assets				
Technology-related	$	907	6 - 14	14% - 23%
Other intangible assets		31	6 - 13	13% - 15%
Indefinite-lived intangible assets				
IPR&D		213	N/A	15%
	$	**1,152**		

2017 Acquisitions

Apama Medical Inc.

On October 11, 2017, we announced the closing of our acquisition of Apama Medical Inc. (Apama), a privately-held company developing the Apama™ Radiofrequency single-shot Balloon Catheter System for the treatment of atrial fibrillation. The transaction price consisted of an upfront cash payment of approximately $175 million and up to approximately $125 million in payments contingent upon clinical and regulatory milestones. Apama is part of our Electrophysiology business.

Symetis SA

On May 16, 2017, we announced the closing of our acquisition of Symetis SA (Symetis), a privately-held Swiss structural heart company focused on minimally-invasive TAVR devices. The transaction price consisted of an upfront cash payment of approximately $430 million. Symetis is part of our Interventional Cardiology business.

Purchase Price Allocation

We accounted for these acquisitions as a business combination and, in accordance with FASB ASC Topic 805, *Business Combinations*, we recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date. The components of the aggregated purchase prices are as follows for our 2017 acquisitions as of December 31, 2018:

(in millions)		
Payment for acquisitions, net of cash acquired	$	560
Fair value of contingent consideration		72
	$	**632**

The following summarizes the aggregated purchase price allocations for our 2017 acquisitions as of December 31, 2018:

(in millions)		
Goodwill	$	287
Amortizable intangible assets		278
Indefinite-lived intangible assets		186
Other assets acquired		44
Liabilities assumed		(61)
Deferred tax liabilities		(102)
	$	**632**

We allocated a portion of the purchase prices to specific intangible asset categories as follows:

		Amount Assigned *(in millions)*	**Amortization Period** *(in years)*	**Risk-Adjusted Discount Rates used in Purchase Price Allocation**
Amortizable intangible assets				
Technology-related	$	268	13	24%

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Other intangible assets		10	2 - 13	24%
Indefinite-lived intangible assets				
IPR&D	$	186	N/A	15%
	$	**464**		

2016 Acquisitions

EndoChoice Holdings, Inc.

On November 22, 2016, we announced the closing of our acquisition of EndoChoice Holdings, Inc. (EndoChoice), an Alpharetta, Georgia based company focused on the development and commercialization of infection control products, pathology services and single-use devices for specialists treating a wide range of gastrointestinal (GI) conditions. The transaction price consisted of an upfront cash payment of approximately $213 million, or $8.00 per share, and repayment of EndoChoice's existing senior term loan facility totaling $43 million and related acquisition fees and expenses. EndoChoice is part of our Endoscopy business.

In addition, we completed other individually immaterial acquisitions during 2016 for total consideration of $189 million in cash at closing plus aggregate contingent consideration of up to $125 million.

Purchase Price Allocation

We accounted for these acquisitions as a business combination and, in accordance with FASB ASC Topic 805, we recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date. The components of the aggregated purchase prices are as follows:

(in millions)		
Payment for acquisitions, net of cash acquired	$	365
Fair value of contingent consideration		50
Fair value of debt repaid		43
	$	**458**

The following summarizes the aggregated purchase price allocations for our 2016 acquisitions:

(in millions)		
Goodwill	$	204
Amortizable intangible assets		228
Other assets acquired		83
Liabilities assumed		(57)
	$	**458**

We allocated a portion of the purchase prices to specific intangible asset categories as follows:

		Amount Assigned *(in millions)*	**Weighted Average Amortization Period** *(in years)*	**Risk-Adjusted Discount Rates used in Purchase Price Allocation**
Amortizable intangible assets				
Technology-related	$	176	9 - 13	11% - 20%
Customer relationships		51	9 - 13	11% - 12%
Other intangible assets		1	4	11%

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

$	**228**

For our 2018, 2017 and 2016 acquisitions, our technology-related intangible assets consist of technical processes, intellectual property and institutional understanding with respect to products and processes that we will leverage in future products or processes and will carry forward from one product generation to the next. We used the multi-period excess earnings method, a variation of the income approach and relief from royalty approach to derive the fair value of the technology-related intangible assets and are amortizing them on a straight-line basis over their assigned estimated useful lives.

Other intangible assets primarily include acquired customer relationships and tradenames. Customer relationships represent the estimated fair value of non-contractual customer, payor and distributor relationships. Customer relationships are direct relationships with physicians and hospitals performing procedures with the acquired products, payor relationships are contracts and relationships with healthcare payors relating to reimbursement of services and distributor relationships are relationships with third parties used

to sell the acquired products, all as of the acquisition date. These relationships were valued separately from goodwill because there is a history and pattern of conducting business with customers and distributors. We used the income approach or the replacement cost and lost profits methodology to derive the fair value of the customer relationships. The customer relationships intangible assets are amortized on a straight-line basis over their assigned estimated useful lives. Tradenames include brand names that we expect to continue using in our product portfolio and related marketing materials. The tradenames are valued using a relief from royalty methodology and are amortized on a straight-line basis over their assigned estimated useful lives.

We believe that the estimated intangible asset values represent the fair value at the date of acquisition and do not exceed the amount a third party would pay for the assets. These fair value measurements are based on significant unobservable inputs, including management estimates and assumptions and, accordingly, are classified as Level 3 within the fair value hierarchy prescribed by FASB ASC Topic 820, *Fair Value Measurements and Disclosures*.

Goodwill was established due primarily to synergies expected to be gained from leveraging our existing operations as well as revenue and cash flow projections associated with future technologies and has been allocated to our reportable segments based on the relative expected benefit. Based on preliminary estimates, the goodwill recorded related to our 2018 acquisitions is not deductible for tax purposes. The goodwill recorded related to our 2017 acquisitions is not deductible for tax purposes. Of the goodwill recorded related to our 2016 acquisitions, $116 million is deductible for tax purposes. Refer to *Note C - Goodwill and Other Intangible Assets* for more information related to goodwill allocated to our reportable segments.

Contingent Consideration

Changes in the fair value of our contingent consideration liability were as follows:

(in millions)		
Balance as of December 31, 2016	**$**	**204**
Amounts recorded related to current year acquisitions		94
Contingent consideration expense (benefit)		(80)
Contingent consideration payments		(48)
Balance as of December 31, 2017	**$**	**169**
Amounts recorded related to current year acquisitions		248
Purchase price adjustments related to prior year acquisitions		(22)
Contingent consideration expense (benefit)		(21)
Contingent consideration payments		(28)
Balance as of December 31, 2018	**$**	**347**

As of December 31, 2018, the maximum amount of future contingent consideration (undiscounted) that we could be required to pay was approximately $873 million. The maximum amount of future contingent consideration (undiscounted) decreased approximately $447 million compared to the amount as of December 31, 2017 due primarily to the expiration of certain contingent consideration arrangements in 2018.

The recurring Level 3 fair value measurements of our contingent consideration liabilities include the following significant unobservable inputs:

Contingent Consideration Liabilities	Fair Value as of December 31, 2018	Valuation Technique	Unobservable Input	Range
R&D, Regulatory and Commercialization-based Milestones	$189 million	Discounted Cash Flow	Discount Rate Probability of Payment	3% - 4% 17% - 100%

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

			Projected Year of Payment	2019 - 2022
Revenue-based Payments	$158 million	Discounted Cash Flow	Discount Rate Probability of Payment Projected Year of Payment	11% - 15% 60% - 100% 2019 - 2026

Projected contingent payment amounts related to some of our R&D, commercialization-based and revenue-based milestones are discounted back to the current period using a Discounted Cash Flow model. Projected revenues are based on our most recent internal operational budgets and strategic plans. Increases or decreases in projected revenues, probabilities of payment, discount rates or the time until payment may result in materially different fair value measurements.

Strategic Investments

The aggregate carrying amounts of our strategic investments were comprised of the following categories:

	As of	
(in millions)	**December 31, 2018**	**December 31, 2017**
Equity method investments	$ 303	$ 209
Measurement alternative investments	94	81
Publicly-held securities	—	15
Notes receivable	26	47
	$ 424	**$ 353**

These investments are classified as *Other long-term assets* within our accompanying consolidated balance sheets, in accordance with U.S. GAAP and our accounting policies.

As of December 31, 2018, the cost of our aggregated equity method investments exceeded our share of the underlying equity in net assets by approximately $334 million, which represents amortizable intangible assets, IPR&D, deferred tax liabilities and goodwill.

As of December 31, 2017, the cost of our aggregated equity method investments exceeded our share of the underlying equity in net assets by approximately $212 million, which represents amortizable intangible assets, IPR&D, deferred tax liabilities and goodwill.

NOTE C – GOODWILL AND OTHER INTANGIBLE ASSETS

The gross carrying amount of goodwill and other intangible assets and the related accumulated amortization for intangible assets subject to amortization and accumulated write-offs of goodwill are as follows:

	As of December 31, 2018		As of December 31, 2017	
(in millions)	**Gross Carrying Amount**	**Accumulated Amortization/Write-offs**	**Gross Carrying Amount**	**Accumulated Amortization/Write-offs**
Amortizable intangible assets				
Technology-related	$ 10,197	$ (5,266)	$ 9,386	$ (4,880)
Patents	520	(393)	517	(379)
Other intangible assets	1,666	(958)	1,633	(838)
	$ 12,383	**$ (6,617)**	**$ 11,536**	**$ (6,097)**
Indefinite-lived intangible assets				
Goodwill	$ 17,811	$ (9,900)	$ 16,898	$ (9,900)
IPR&D	486	—	278	—

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Technology-related	120	—	120	—
	$ 18,417	**$ (9,900)**	**$ 17,295**	**$ (9,900)**

In the third quarter of 2018, we performed our annual impairment test of all IPR&D projects and our indefinite-lived core technology assets and determined that the assets were not impaired. In addition, we verified the classification as indefinite-lived assets continues to be appropriate.

Intangible asset impairment charges were immaterial in 2018, 2017 and 2016.

Effective January 1, 2018, we reclassified our Neuromodulation operating segment and associated goodwill balance from our MedSurg reportable segment to our Rhythm and Neuro reportable segment as discussed in *Note A – Significant Accounting Policies*. This change did not impact our total goodwill carrying value. The following represents our goodwill balance by global reportable segment:

(in millions)	MedSurg	Rhythm and Neuro	Cardiovascular	Total
Balance as of December 31, 2016	**$ 2,875**	**$ 290**	**$ 3,513**	**$ 6,678**
Impact of foreign currency fluctuations and other changes in carry amount	2	1	9	12
Goodwill acquired	—	126	182	308
Balance as of December 31, 2017	**$ 2,877**	**$ 417**	**$ 3,704**	**$ 6,998**
Impact of reportable segment revisions	(1,379)	1,379	—	—
Impact of foreign currency fluctuations and other changes in carry amount	(3)	(22)	(3)	(29)
Goodwill acquired	568	150	224	942
Balance as of December 31, 2018	**$ 2,063**	**$ 1,924**	**$ 3,925**	**$ 7,911**

We did not have any goodwill impairments in 2018, 2017 or 2016.

Estimated *Amortization expense* for each of the five succeeding fiscal years based upon our amortizable intangible asset portfolio as of December 31, 2018 is as follows (in millions):

Fiscal Year	
2019	$ 639
2020	635
2021	599
2022	571
2023	551

NOTE D – HEDGING ACTIVITIES AND FAIR VALUE MEASUREMENTS

Derivative Instruments and Hedging Activities

We address market risk from changes in foreign currency exchange rates and interest rates through risk management programs which include the use of derivative financial instruments. We operate these programs pursuant to documented corporate risk management policies and do not enter into derivative transactions for speculative purposes. Our derivative instruments do not subject our earnings to material risk, as the gains or losses on these derivatives generally offset losses or gains recognized on the hedged item.

We manage concentration of counterparty credit risk by limiting acceptable counterparties to major financial institutions with investment grade credit ratings, limiting the amount of credit exposure to individual counterparties and by actively monitoring counterparty credit ratings and the amount of individual credit exposure. We also employ master netting arrangements that limit the risk of counterparty non-payment on a particular settlement date to the net gain that would have otherwise been received from the counterparty.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Although not completely eliminated, we do not consider the risk of counterparty default to be significant as a result of these protections. Further, none of our derivative instruments are subject to collateral or other security arrangements, nor do they contain provisions that are dependent on our credit ratings from any credit rating agency.

Currency Derivative Instruments

Risk Management Strategy

Our risk from changes in currency exchange rates consists primarily of monetary assets and liabilities, forecast intercompany and third-party transactions and net investments in certain subsidiaries. We manage currency exchange rate risk at a consolidated level to reduce the cost of hedging by taking advantage of offsetting transactions. We employ derivative instruments, primarily forward currency contracts, to reduce the risk to our earnings and cash flows associated with changes in currency exchange rates.

The success of our currency risk management program depends, in part, on forecast transactions denominated primarily in British pound sterling, Euro and Japanese yen. We may experience unanticipated currency exchange gains or losses to the extent the actual activity is different than forecast. In addition, changes in currency exchange rates related to any unhedged transactions may impact our earnings and cash flows.

Derivative Designations and Hedging Relationships

Certain of our currency derivative instruments are designated as cash flow hedges under FASB ASC Topic 815, *Derivatives and Hedging*, and are intended to protect the U.S. dollar value of forecasted transactions. The gain or loss on a derivative instrument designated as a cash flow hedge is recorded in the *Net change in derivative financial instruments* component of *Other comprehensive income (loss), net of tax (OCI)* on our consolidated statements of comprehensive income (loss) until the underlying third-party transaction occurs. When the underlying third-party transaction occurs, we recognize the gain or loss in earnings within the *Cost of products sold* caption of our consolidated statements of operations. In the event the hedging relationship is no longer effective, or if the hedged forecast transaction becomes no longer probable of occurring, we reclassify the gains or losses within *AOCI* to earnings at that time.

We also designate certain currency forward contracts as net investment hedges to hedge a portion of our net investments in certain of our entities with functional currencies denominated in the Euro, Swiss franc, and Japanese yen. We have elected to use the spot method to assess effectiveness for our derivatives that are designated as net investment hedges. Under the spot method, the change in fair value attributable to changes in the spot rate is recorded in the *Foreign currency translation adjustment (CTA)* component of *OCI*. We have elected to exclude the spot-forward difference from the assessment of hedge effectiveness and are amortizing this amount separately, as calculated at the date of designation, on a straight-line basis over the term of the currency forward contracts. Amortization of the spot-forward difference is then reclassified from *AOCI* to current period earnings as a reduction to *Interest expense* on our consolidated statements of operations.

We also use forward currency contracts that are not part of designated hedging relationships under FASB ASC Topic 815 as a part of our strategy to manage our exposure to currency exchange rate risk related to monetary assets and liabilities and related forecast transactions. These non-designated currency forward contracts have an original time to maturity consistent with the hedged currency transaction exposures, generally less than one year, and are marked-to-market with changes in fair value recorded to earnings within the *Other, net* caption of our consolidated statements of operations.

Certain of our non-designated forward currency contracts outstanding as of December 31, 2018, relate to hedging a portion of the purchase price of the proposed BTG Acquisition ($2.550 billion notional value as of December 31, 2018). During the first quarter of 2019, we entered into additional non-designated forward currency contracts, after which our combined notional value is £3.311 billion, which represents the full purchase price for the proposed BTG Acquisition.

Interest Rate Derivative Instruments

Risk Management Strategy

Our interest rate risk relates primarily to U.S. dollar borrowings partially offset by U.S. dollar cash investments. We use interest rate derivative instruments to manage our earnings and cash flow exposure to changes in interest rates. Under these agreements we and the counterparty, at specified intervals, exchange the difference between fixed and floating interest amounts calculated by reference to an agreed-upon notional principal amount. We designate these derivative instruments either as fair value or cash flow hedges in accordance with FASB ASC Topic 815.

Derivative Designations and Hedging Relationships

Certain of our interest rate derivative instruments are designated as cash flow hedges and are intended to manage our earnings and cash flow exposure to changes in the benchmark interest rate in connection with the forecasted issuance of fixed-rate debt. During the fourth quarter of 2018, we entered into interest rate derivative contracts, designated as cash flow hedges, having a notional amount of $1.000 billion to hedge interest rate risk. We record the changes in the fair value of the derivatives within *OCI* until the underlying hedged transaction occurs, at which time we recognize the gain or loss within *Interest expense* over the same period that the hedged items affect earnings, so long as the hedge relationship remains effective. If we determine the hedging relationship is no longer effective, or if the hedged forecast transaction becomes no longer probable of occurring, we reclassify the

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

amount of gains or losses from *AOCI* to earnings at that time. Prior to the adoption of ASC Update No. 2017-12, *Derivatives and Hedging* (Topic 815), the ineffective portion, if any, was recognized in earnings in the period in which the hedging relationship exhibited ineffectiveness.

We previously terminated interest rate derivative instruments that were designated as cash flow hedges and are reclassifying the amortization of the gains or losses from *AOCI* into earnings as a component of *Interest expense* over the same period that the hedged items affect earnings, so long as the hedge relationship remains effective. The balance of the deferred gains on our terminated cash flow hedges within *AOCI* was immaterial as of December 31, 2018 and December 31, 2017. We recognized immaterial gains in *Interest expense* relating to the amortization of the terminated cash flow hedges in the current and prior periods.

We had no interest rate derivative instruments designated as fair value hedges outstanding as of December 31, 2018 and December 31, 2017. We previously terminated interest rate derivative instruments that were designated as fair value hedges and are recognizing the amortization of the gains or losses originally recorded within the *Long-term debt* caption on our consolidated balance sheets into earnings as a component of *Interest expense* over the same period that the discount or premium associated with the hedged items affect earnings. In the event that we designate outstanding interest rate derivative instruments as fair value hedges, we record the changes in the fair values of interest rate derivatives designated as fair value hedges and of the underlying hedged debt instruments in *Interest expense*, which generally offset. The balance of the deferred gains on our terminated fair value hedges within *Long-term debt* was immaterial as of December 31, 2018 and December 31, 2017. We recognized immaterial gains in *Interest expense* relating to the amortization of the terminated fair value hedges in the current and prior periods.

The following table presents the contractual amounts of our derivative instruments outstanding:

		As of	
(in millions)	**FASB ASC Topic 815 Designation**	**December 31, 2018**	**December 31, 2017**
Forward currency contracts	Cash flow hedge	$ 3,962	$ 3,252
Forward currency contracts	Net investment hedge	1,483	—
Forward currency contracts	Non-designated	5,880	2,671
Interest rate derivative contracts	Cash flow hedge	1,000	—
Total Notional Outstanding		**$ 12,326**	**$ 5,923**

The remaining time to maturity as of December 31, 2018 is within 60 months for all designated forward currency contracts and generally less than one year for all non-designated forward currency contracts.

The following presents the effect of our derivative instruments designated as cash flow and net investment hedges under FASB ASC Topic 815 on our accompanying consolidated statements of operations. Refer to *Note P – Changes in Other Comprehensive Income* for the total amounts relating to derivative instruments presented within the consolidated statements of comprehensive income (loss).

	Effect of Hedging Relationships on Accumulated Other Comprehensive Income							
	Amount Recognized in OCI on Derivative			Consolidated Statements of Operations (1)		Amount Reclassified from AOCI into Earnings		
	Pre-Tax Gain (Loss)	Tax Benefit (Expense)	Gain (Loss) Net of Tax	Location of Amount Reclassified	Total Amount of Line Item Presented	Pre-Tax (Gain) Loss	Tax (Benefit) Expense	(Gain) Loss Net of Tax
Year Ended December 31, 2018								
Forward currency contracts								
Cash flow hedges	$ 167	$ (38)	$ 130	Cost of products sold	$ 2,813	$ 19	$ (4)	$ 15
Net investment hedges (2)	56	(13)	43	Interest expense	241	(27)	6	(21)
Interest rate derivative contracts								
Cash flow hedges	(44)	10	(34)	Interest expense	241	(1)	—	(1)
Year Ended December 31, 2017								
Forward currency contracts								
Cash flow hedges	$ (101)	$ 37	$ (65)	Cost of products sold	$ 2,593	$ (64)	$ 23	$ (41)
Interest rate derivative contracts								
Cash flow hedges	—	—	—	Interest expense	229	(1)	—	(1)
Year Ended December 31, 2016								
Forward currency contracts								
Cash flow hedges	$ 65	$ (23)	$ 40	Cost of products sold	$ 2,424	$ (133)	$ 48	$ (84)
Interest rate derivative contracts								
Cash flow hedges	—	—	—	Interest expense	233	(1)	—	(1)

(1) In all periods presented in the table above, the pre-tax (gain) loss amounts reclassified from *AOCI* to earnings represent the effect of the hedging relationships on earnings. All other amounts included in earnings related to hedging relationships were immaterial.

(2) For our outstanding net investment hedges, the net gain or loss reclassified from *AOCI* to earnings as a reduction of *Interest expense* represents the straight-line amortization of the excluded component as calculated at the date of designation. This initial value of the excluded component has been excluded from the assessment of effectiveness in accordance with FASB ASC Topic 815. In the current period, we did not recognize any gains or losses on the components included in the assessment of hedge effectiveness in *AOCI* or earnings.

As of December 31, 2018, pre-tax net gains or losses for our derivative instruments designated, or previously designated, as cash flow and net investment hedges under FASB ASC Topic 815 that may be reclassified from *AOCI* to earnings within the next twelve months are presented below (in millions):

Designated Derivative Instrument	FASB ASC Topic 815 Designation	Location on Consolidated Statements of Operations	Amount of Pre-Tax Gain (Loss) that may be Reclassified to Earnings
Forward currency contracts	Cash flow hedge	Cost of products sold	56
Forward currency contracts	Net investment hedge	Interest expense	41
Interest rate derivative contracts	Cash flow hedge	Interest expense	(43)

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Net gains and losses on currency hedge contracts not designated as hedging instruments offset by net gains and losses from currency transaction exposures are presented below:

(in millions)	Location on Consolidated Statements of Operations	Year Ended December 31, 2018	2017	2016
Net gain (loss) on currency hedge contracts	Other, net	$ 41	$ (25)	$ (20)
Net gain (loss) on currency transaction exposures	Other, net	(30)	10	7
Net currency exchange gain (loss)		**$ 11**	**$ (15)**	**$ (13)**

Fair Value Measurements

FASB ASC Topic 815 requires all derivative instruments to be recognized at their fair values as either assets or liabilities on the balance sheet. We determine the fair value of our derivative instruments using the framework prescribed by FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, and considering the estimated amount we would receive or pay to transfer these instruments at the reporting date with respect to current currency exchange rates, interest rates, the creditworthiness of the counterparty for unrealized gain positions and our own creditworthiness for unrealized loss positions. In certain instances, we may utilize financial models to measure fair value of our derivative instruments. In doing so, we use inputs that include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, other observable inputs for the asset or liability and inputs derived principally from, or corroborated by, observable market data by correlation or other means. The following are the balances of our derivative assets and liabilities:

(in millions)	Location on Consolidated Balance Sheets (1)	As of December 31, 2018	December 31, 2017
Derivative Assets:			
Designated Derivative Instruments			
Forward currency contracts	Other current assets	$ 55	$ 7
Forward currency contracts	Other long-term assets	183	57
		237	64
Non-Designated Derivative Instruments			
Forward currency contracts	Other current assets	67	18
Total Derivative Assets		**$ 304**	**$ 82**
Derivative Liabilities:			
Designated Derivative Instruments			
Forward currency contracts	Other current liabilities	$ 2	$ 37
Forward currency contracts	Other long-term liabilities	3	33
Interest rate contracts	Other current liabilities	44	—
		49	69
Non-Designated Derivative Instruments			
Forward currency contracts	Other current liabilities	31	21
Total Derivative Liabilities		**$ 80**	**$ 90**

(1) We classify derivative assets and liabilities as current when the settlement date of the derivative contract is one year or less.

Recurring Fair Value Measurements

On a recurring basis, we measure certain financial assets and financial liabilities at fair value based upon quoted market prices. Where quoted market prices or other observable inputs are not available, we apply valuation techniques to estimate fair value. FASB ASC Topic 820 establishes a three-level valuation hierarchy for disclosure of fair value measurements. The category of a financial asset or a financial liability within the valuation hierarchy is based upon the lowest level of input that is significant to the measurement of fair value. The three levels of the hierarchy are defined as follows:

- Level 1 – Inputs to the valuation methodology are quoted market prices for identical assets or liabilities.
- Level 2 – Inputs to the valuation methodology are other observable inputs, including quoted market prices for similar assets or liabilities and market-corroborated inputs.
- Level 3 – Inputs to the valuation methodology are unobservable inputs based on management's best estimate of inputs market participants would use in pricing the asset or liability at the measurement date, including assumptions about risk.

Assets and liabilities measured at fair value on a recurring basis consist of the following:

	As of							
	December 31, 2018				December 31, 2017			
(in millions)	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets								
Money market and government funds	$ 13	$ —	$ —	$ 13	$ 21	$ —	$ —	$ 21
Publicly-held securities	—	—	—	—	15	—	—	15
Derivative Instruments	—	304	—	304	—	82	—	82
	$ 14	**$ 304**	**$ —**	**$ 318**	**$ 36**	**$ 82**	**$ —**	**$ 118**
Liabilities								
Derivative Instruments	$ —	$ 80	$ —	$ 80	$ —	$ 90	$ —	$ 90
Contingent consideration liability	—	—	347	347	—	—	169	169
	$ —	**$ 80**	**$ 347**	**$ 427**	**$ —**	**$ 90**	**$ 169**	**$ 259**

Our investments in money market and government funds are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices. These investments are classified as *Cash and cash equivalents* within our accompanying consolidated balance sheets, in accordance with U.S. GAAP and our accounting policies. In addition to $13 million invested in money market and government funds as of December 31, 2018, we had $133 million in interest bearing and non-interest-bearing bank accounts. In addition to $21 million invested in money market and government funds as of December 31, 2017, we had $167 million in interest bearing and non-interest bearing bank accounts.

Our recurring fair value measurements using Level 3 inputs relate solely to our contingent consideration liability. Refer to *Note B – Acquisitions and Strategic Investments* for a discussion of the changes in the fair value of our contingent consideration liability.

Non-Recurring Fair Value Measurements

We hold certain assets and liabilities that are measured at fair value on a non-recurring basis in periods after initial recognition. The fair value of a measurement alternative investment is not estimated if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investment. Refer to *Note B – Acquisitions and Strategic Investments* for a discussion of our strategic investments.

Refer to *Note C - Goodwill and Other Intangible Assets* for a discussion of the fair values.

The fair value of our outstanding debt obligations was $7.239 billion as of December 31, 2018 and $5.945 billion as of December 31, 2017. We determined fair value by using quoted market prices for our publicly registered senior notes, classified as Level 1 within the fair value hierarchy, amortized cost for commercial paper and face value for term loans and credit facility borrowings outstanding. Refer to *Note E – Borrowings and Credit Arrangements* for a discussion of our debt obligations.

NOTE E – BORROWINGS AND CREDIT ARRANGEMENTS

We had total debt of $7.056 billion as of December 31, 2018 and $5.616 billion as of December 31, 2017. The debt maturity schedule for our long-term debt obligations is presented below:

(in millions, except interest rates)	Issuance Date	Maturity Date	As of December 31, 2018	As of December 31, 2017	Semi-annual Coupon Rate
January 2020 Notes	December 2009	January 2020	$ 850	$ 850	6.000%
May 2020 Notes	May 2015	May 2020	600	600	2.850%
May 2022 Notes	May 2015	May 2022	500	500	3.375%
October 2023 Notes	August 2013	October 2023	450	450	4.125%
May 2025 Notes	May 2015	May 2025	750	750	3.850%
March 2028 Notes	February 2018	March 2028	1,000	—	4.000%
November 2035 Notes (1)	November 2005	November 2035	350	350	7.000%
January 2040 Notes	December 2009	January 2040	300	300	7.375%
Unamortized Debt Issuance Discount and Deferred Financing Costs		2020 - 2040	(29)	(24)	
Unamortized Gain on Fair Value Hedges		2020-2025	26	38	
Capital Lease Obligation		Various	6	1	
Long-term debt			**$ 4,803**	**$ 3,815**	

Note: The table above does not include unamortized amounts related to interest rate contracts designated as cash flow hedges.

(1) Corporate credit rating improvements may result in a decrease in the adjusted interest rate on our November 2035 Notes to the extent that our lowest credit rating is above BBB- or Baa3. The interest rates on our November 2035 Notes will be permanently reinstated to the issuance rate if the lowest credit ratings assigned to these senior notes is either A- or A3 or higher.

Revolving Credit Facility

On December 19, 2018, we entered into a $2.750 billion revolving credit facility (the 2018 Facility) with a global syndicate of commercial banks and terminated our previous $2.250 billion revolving credit facility (the 2017 Facility), which was scheduled to mature in August 2022. The 2018 Facility will mature on December 19, 2023 with one-year extension options subject to certain conditions. Eurodollar and multicurrency loans bear interest at the Eurocurrency Rate determined for the interest period plus the applicable margin, based on our corporate credit ratings (1.02 percent as of December 31, 2018). ABR loans bear interest at ABR plus the applicable margin of up to 0.40 percent, based on our corporate credit ratings. Under the credit agreement for the 2018 Facility (the 2018 Credit Agreement), we are required to pay a facility fee (0.11 percent as of December 31, 2018) based on our credit ratings and the total amount of revolving credit commitment, regardless of usage of the 2018 Facility. This facility provides backing for the commercial paper program described below. There were no amounts borrowed under our current or prior revolving credit facilities as of December 31, 2018 or December 31, 2017.

Bridge Facility

On November 20, 2018, we entered into the Bridge Facility in aggregate principal amount of £3.315 billion for the purpose of financing the proposed BTG Acquisition. The Bridge Facility is comprised of a £3.115 billion debt bridge facility, borrowings under which mature 364 days from the date of the first borrowing under the Bridge Facility, and a £200 million cash bridge facility, borrowings under which mature 90 days from the date of the first borrowing under the Bridge Facility. Borrowings are available in British pound sterling or U.S. dollar and bear interest at the LIBOR for borrowings in British pound sterling or U.S. dollar, as applicable, or the base rate for borrowings in U.S. dollars, in each case plus an applicable margin based on our public debt ratings. The Bridge Facility also provides for customary ticking fees based on our public debt ratings and duration fees. The

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Bridge Facility requires that we maintain certain financial covenants, as described within *Debt Covenants* below. The Bridge Facility contains customary events of default, which may result in the acceleration of any outstanding commitments and also contains customary United Kingdom (U.K.) certain funds provisions. There were no amounts borrowed under the Bridge Facility as of December 31, 2018. In December 2018, in connection with our new term loans and currency hedging activities, we reduced the debt bridge

facility by an aggregate amount of £1.569 billion to a remaining available amount of £1.546 billion. Refer to *Note B – Acquisitions and Strategic Investments* for a discussion of our currency hedging activities.

Term Loans

On December 19, 2018, we entered into the First Amendment to our $1.000 billion Term Loan Credit Agreement (August 2019 Term Loan), which was originally entered into August 20, 2018, which matures on August 19, 2019 and is presented within *Current debt obligations* in the accompanying consolidated balance sheets. Borrowings under the August 2019 Term Loan bear interest at an annual rate of LIBOR plus 0.65 percent. The August 2019 Term Loan requires that we comply with certain covenants, including financial covenants as described within *Debt Covenants* below. As of December 31, 2018, we had $1.000 billion outstanding under our August 2019 Term Loan. We used the proceeds from the August 2019 Term Loan to repay a portion of our outstanding commercial paper.

On December 19, 2018, we entered into a $2.000 billion senior unsecured delayed-draw term loan facility consisting of a $1.000 billion two-year delayed draw term loan credit facility maturing in two years from the date of the closing of the proposed BTG Acquisition (Two-Year Delayed Draw Term Loan) and a $1.000 billion three-year delayed draw term loan credit facility maturing in three years from the date of the closing of the proposed BTG Acquisition (Three-Year Delayed Draw Term Loan). Borrowings are available in U.S. dollars and bear interest at LIBOR or a base rate in each case plus an applicable margin based on our public debt ratings. We are required to pay customary ticking fees on the average daily unused commitments based on our public debt ratings. The facilities contain customary representations and covenants, as described within *Debt Covenants* below. The facilities contain customary events of default, which may result in the acceleration of any outstanding commitments, and also contains customary U.K. certain funds provisions. Any proceeds from the facilities will be available to refinance in part the commitments outstanding under the Bridge Facility, described above, to finance the proposed BTG Acquisition. As of December 31, 2018, we had no amounts borrowed under the Two-Year Delayed Draw Term Loan or the Three-Year Delayed Draw Term Loan.

Debt Covenants

As of and through December 31, 2018, we were in compliance with all the required covenants related to our debt obligations.

All existing credit arrangements described above require that we maintain certain financial covenants, as follows:

	Covenant Requirement as of December 31, 2018	**Actual as of December 31, 2018**
Maximum leverage ratio (1)	3.75 times	2.56 times

(1) Ratio of total debt to consolidated EBITDA, as defined by the agreements, for the preceding four consecutive fiscal quarters.

Our covenants require that we maintain a maximum leverage ratio of 3.75 times, provided, however, that for the two consecutive fiscal quarters ended immediately following the consummation of a Qualified Acquisition, as defined by each agreement below, the maximum leverage ratio shall be 4.75 times, and then subject to a step-down for each succeeding fiscal quarter end to 4.5 times, 4.25 times, 4.00 times and then back to 3.75 times for each fiscal quarter end thereafter. Our covenants provide for an exclusion from the calculation of consolidated EBITDA, as defined by the agreements, through maturity, of any non-cash charges and up to $500 million in restructuring charges and restructuring-related expenses related to our current or future restructuring plans. As of December 31, 2018, we had $350 million of the restructuring charge exclusion remaining. In addition, any cash litigation payments (net of any cash litigation receipts), as defined by the agreements, are excluded from the calculation of consolidated EBITDA, as defined by the agreements, provided that the sum of any excluded net cash litigation payments do not exceed $2.624 billion in the aggregate. As of December 31, 2018, we had approximately $1.191 billion of the legal exclusion remaining.

A Qualified Acquisition, as defined by the 2018 Credit Agreement and August 2019 Term Loan, includes but is not limited to the proposed BTG Acquisition. A Qualified Acquisition, as defined by the Bridge Facility, Two-Year Delayed Draw Term Loan and Three-Year Delayed Draw Term Loan, is limited to the proposed BTG Acquisition and any other transaction permitted under the Bridge Facility and consummated on or after the Closing date, as defined by the Bridge Facility.

Any inability to maintain compliance with these covenants could require us to seek to renegotiate the terms of our credit facility or seek waivers from compliance with these covenants, both of which could result in additional borrowing costs. Further, there can be no assurance that our lenders would agree to such new terms or grant such waivers on terms acceptable to us. In this case, all credit facility commitments would terminate, and any amounts borrowed under the facility would become immediately due and payable. Furthermore, any termination of our credit facility may negatively impact the credit ratings assigned to our commercial paper program which may impact our ability to refinance any then outstanding commercial paper as it becomes due and payable.

Commercial Paper

	As of December 31,	
	2018	2017
Commercial paper outstanding *(in millions)*	$ 1,248	$ 1,197
Maximum borrowing capacity *(in millions)*	2,750	2,250
Borrowing capacity available *(in millions)*	1,502	1,053
Weighted average maturity *(in days)*	27	38
Weighted average yield	3.04%	1.85%

Outstanding commercial paper directly reduces borrowing capacity and is backed by the 2018 Facility.

Senior Notes

We had senior notes outstanding of $4.800 billion as of December 31, 2018 and $4.400 billion as of December 31, 2017.

In February 2018, we completed an offering of $1.000 billion in aggregate principal amount of 4.000% senior notes, due March 2028. We used a portion of the net proceeds from the offering to repay the $600 million plus accrued interest of our 2.650% senior notes due in October 2018, which were classified as short-term debt as of December 31, 2017. The remaining proceeds were used to repay a portion of our outstanding commercial paper.

Our senior notes were issued in public offerings, are redeemable prior to maturity and are not subject to sinking fund requirements. Our senior notes are unsecured, unsubordinated obligations and rank on parity with each other. These notes are effectively junior to borrowings under our credit and security facility, to the extent if borrowed by our subsidiaries and to liabilities of our subsidiaries (see *Other Arrangements* below).

Our $4.450 billion of senior notes issued in 2009, 2013, 2015 and 2018 contain a change-in-control provision, which provides that each holder of the senior notes may require us to repurchase all or a portion of the notes at a price equal to 101 percent of the aggregate repurchased principal, plus accrued and unpaid interest, if a rating event, as defined in the indenture, occurs as a result of a change-in-control, as defined in the indenture. Any other credit rating changes may impact our borrowing cost, but do not require us to repay any borrowings.

Other Arrangements

On December 19, 2018 and effective on December 20, 2018, we terminated our $400 million credit and security facility secured by our U.S. trade receivables. We had no amounts outstanding under this facility as of December 31, 2017.

We have accounts receivable factoring programs in certain European countries and with commercial banks in Japan which include promissory notes discounting programs. We account for our factoring programs as sales under FASB ASC Topic 860, *Transfers and Servicing*. We have no retained interest in the transferred receivables, other than collection and administration, and once sold, the accounts receivable are no longer available to satisfy creditors in the event of bankruptcy. Amounts de-recognized for accounts and notes receivable, which are excluded from *Trade accounts receivable, net* in the accompanying consolidated balance sheets, are aggregated by contract denominated currency below (in millions):

As of December 31, 2018	As of December 31, 2017

Factoring Arrangements	Capacity (1)	Amount De-recognized	Weighted Average Interest Rate	Capacity (1)	Amount De-recognized	Weighted Average Interest Rate
Euro denominated	$ 474	$ 165	2.7%	$ 456	$ 171	1.8%
Yen denominated (2)	273	195	0.9%	195	157	1.3%

(1) The capacities are translated from local currency to U.S. dollar using the spot rates on the last business day of each period.

(2) The factoring arrangements denominated in Japanese yen consist of two arrangements, one with a maximum capacity of 22.000 billion yen, which has been discontinued in the second quarter of 2018, and a new arrangement with a maximum capacity of 30.000 billion yen entered into in March 2018.

NOTE F – LEASES AND OTHER PURCHASE OBLIGATIONS

Rent expense amounted to $92 million in 2018, $88 million in 2017 and $80 million in 2016.

Future minimum rental commitments as of December 31, 2018 under all noncancellable lease agreements, including capital leases, were as follows:

(in millions)		
2019	$	73
2020		61
2021		47
2022		39
2023		31
Thereafter		111
	$	**362**

Future minimum purchase obligations as of December 31, 2018, were as follows:

(in millions)		
2019	$	362
2020		23
2021		12
2022		3
2023		2
Thereafter		7
	$	**409**

NOTE G – RESTRUCTURING-RELATED ACTIVITIES

2019 Restructuring Plan

On November 15, 2018, the Board of Directors approved, and we committed to a new global restructuring program (the 2019 Restructuring Plan). The 2019 Restructuring Plan is intended to support our effort to improve operating performance and meet anticipated market demands by ensuring that we are appropriately structured and resourced to deliver sustainable value to patients and customers. Key activities under the 2019 Restructuring Plan include supply chain network optimization intended to maximize our global manufacturing and distribution network capacity and building functional capabilities that support business growth. These activities are expected to be initiated in 2019, with the majority of activity expected to be complete by the end of 2021.

The following table provides a summary of our estimates of total pre-tax charges associated with the 2019 Restructuring Plan by major type of cost:

Type of Cost	**Total Estimated Amount Expected to be Incurred**
Restructuring charges:	

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Termination benefits	$75 million to $100 million
Other (1)	$25 million to $50 million
Restructuring-related expenses:	
Other (2)	$100 million to $150 million
	$200 million to $300 million

(1) Consists primarily of consultant fees and costs associated with contractual cancellations.
(2) Comprised of other costs directly related to the restructuring program, including program management, accelerated depreciation, fixed asset write-offs, and costs to transfer product lines among facilities.

Approximately $180 million to $280 million of these charges are expected to result in cash outlays.

2016 Restructuring Plan

On June 6, 2016, our Board of Directors approved, and we committed to a restructuring initiative (the 2016 Restructuring Plan). The 2016 Restructuring Plan is intended to develop global commercialization, technology and manufacturing capabilities in key growth markets, build on our Plant Network Optimization (PNO) strategy which is intended to simplify our manufacturing plant structure by transferring certain production lines among facilities and expand operational efficiencies in support of our operating income margin goals. Key activities under the 2016 Restructuring Plan include strengthening global infrastructure through evolving global real estate assets and workplaces, developing global commercial and technical competencies, enhancing manufacturing and distribution expertise in certain regions and continuing implementation of our PNO strategy. These activities were initiated in the second quarter of 2016 and the majority of the costs associated with this Plan were completed by the end of 2018. We revised the original estimate for the costs and savings associated with the program in the first quarter of 2018, as approved by the Board of Directors.

The following table provides a summary of our estimates of total pre-tax charges associated with the 2016 Restructuring Plan by major type of cost:

Type of cost	Total Estimated Amount Expected to be Incurred
Restructuring charges:	
Termination benefits	$80 million to $90 million
Other (1)	$25 million to $50 million
Restructuring-related expenses:	
Other (2)	$170 million to $185 million
	$275 million to $325 million

(1) Consists primarily of consulting fees and costs associated with contract cancellations.
(2) Comprised of other costs directly related to the 2016 Restructuring Plan, including program management, accelerated depreciation, fixed asset write-offs and costs to transfer product lines among facilities.

Approximately $250 million to $300 million of these charges are estimated to result in cash outlays.

The following presents the restructuring and restructuring-related charges (credits) by major type and line item within our accompanying consolidated statements of operations (in millions):

Year Ended December 31, 2018	Termination Benefits	Transfer Costs	Other	Total
Restructuring charges	**$ 32**	**$ —**	**$ 4**	**$ 36**
Restructuring-related expenses:				
Cost of products sold	—	47	—	47
Selling, general and administrative expenses	—	—	12	12
	—	47	12	**59**
	$ 32	**$ 47**	**$ 16**	**$ 96**

Year Ended December 31, 2017	Termination Benefits	Transfer Costs	Other	Total
Restructuring charges	**$ 25**	$ —	**$ 12**	**$ 37**

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Restructuring-related expenses:				
Cost of products sold	—	45	—	45
Selling, general and administrative expenses	—	—	13	13
	—	**45**	**13**	**58**
	$ 25	**$ 45**	**$ 25**	**$ 95**

Year Ended December 31, 2016	Termination Benefits	Transfer Costs	Other	Total
Restructuring charges	**$ 19**	**$ —**	**$ 9**	**$ 28**
Restructuring-related expenses:				
Cost of products sold	—	34	—	34
Selling, general and administrative expenses	—	—	16	16
	—	34	**16**	**50**
	$ 19	**$ 34**	**$ 25**	**$ 78**

Expenses in 2016 include costs associated with the 2016 Restructuring Plan and expenses associated with other substantially completed plans.

The following table presents cumulative restructuring and restructuring-related charges incurred as of December 31, 2018, related to our 2016 Restructuring Plan by major type:

(in millions)	2016 Restructuring Plan
Termination benefits	$ 81
Other (1)	20
Total restructuring charges	**100**
Transfer costs	107
Other (2)	28
Restructuring-related charges	**136**
	$ 236

(1) Consists primarily of consulting fees and costs associated with contract cancellations.
(2) Comprised of other costs directly related to our Restructuring Plans, including program management, accelerated depreciation, fixed asset write-offs and costs to transfer product lines among facilities.

Cash payments associated with our 2016 Restructuring Plan were made using cash generated from operations and are comprised of the following:

(in millions)	2016 Restructuring Plan
Year Ended December 31, 2018	
Termination benefits	$ 32
Transfer costs	47
Other	20
	$ 100

NOTE H – SUPPLEMENTAL BALANCE SHEET INFORMATION

Components of selected captions in our accompanying consolidated balance sheets are as follows:

Trade accounts receivable, net

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

(in millions)	As of December 31, 2018	As of December 31, 2017
Accounts receivable	$ 1,676	$ 1,645
Allowance for doubtful accounts	(68)	(68)
Allowance for sales returns (1)	—	(30)
	$ 1,608	**$ 1,548**

(1) Due to the adoption of FASB ASC Topic 606 effective January 1, 2018, the allowance for sales returns has been prospectively reclassified from *Trade accounts receivable, net* to *Other current liabilities* within the consolidated balance sheets. Prior period balances remain unchanged.

The following is a rollforward of our allowance for doubtful accounts:

(in millions)	Year Ended December 31, 2018	2017	2016
Beginning balance	**$ 68**	**$ 73**	**$ 75**
Net charges to expenses	19	14	9
Utilization of allowances	(19)	(18)	(11)
Ending balance	**$ 68**	**$ 68**	**$ 73**

Inventories

(in millions)	As of December 31, 2018	December 31, 2017
Finished goods	$ 760	$ 685
Work-in-process	100	110
Raw materials	306	284
	$ 1,166	**$ 1,078**

Property, plant and equipment, net

(in millions)	As of December 31, 2018	December 31, 2017
Land	$ 97	$ 102
Buildings and improvements	1,100	1,120
Equipment, furniture and fixtures	3,224	3,183
Capital in progress	319	219
	4,740	4,625
Less: accumulated depreciation	2,958	2,928
	$ 1,782	**$ 1,697**

Depreciation expense was $296 million in 2018, $279 million in 2017 and $270 million in 2016.

Accrued expenses

(in millions)	As of December 31, 2018	December 31, 2017
Legal reserves	$ 712	$ 1,176
Payroll and related liabilities	630	591

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Accrued contingent consideration	138	36
Other	767	653
	$ 2,246	**$ 2,456**

Other long-term liabilities

	As of	
(in millions)	**December 31, 2018**	**December 31, 2017**
Accrued income taxes	$ 739	$ 1,275
Legal reserves	217	436
Accrued contingent consideration	209	133
Other	717	525
	$ 1,882	**$ 2,370**

NOTE I – INCOME TAXES

Our *Income (loss) before income taxes* consisted of the following:

	Year Ended December 31,		
(in millions)	**2018**	**2017**	**2016**
Domestic	$ 35	$ (408)	$ (1,019)
Foreign	1,387	1,341	1,196
	$ 1,422	**$ 933**	**$ 177**

The related benefit for income taxes consisted of the following:

	Year Ended December 31,		
(in millions)	**2018**	**2017**	**2016**
Current			
Federal	$ (221)	$ 320	$ 31
State	(27)	9	6
Foreign	160	255	136
	(87)	584	173
Deferred			
Federal	(124)	272	(337)
State	4	1	(14)
Foreign	(42)	(28)	8
	(162)	244	(343)
	$ (249)	**$ 828**	**$ (170)**

The reconciliation of income taxes at the federal statutory rate to the actual benefit for income taxes is as follows:

	Year Ended December 31,		
	2018	**2017**	**2016**
		(reclassified)[1]	(reclassified)[1]
U.S. federal statutory income tax rate	21.0 %	35.0 %	35.0 %
State income taxes, net of federal benefit	0.4 %	(1.0)%	(2.1)%
Domestic taxes on foreign earnings	0.5 %	0.4 %	0.5 %
Effect of foreign taxes	(8.3)%	(38.9)%	(142.1)%
Acquisition-related	2.1 %	(1.7)%	11.3 %

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Research credit	(2.6)%	(2.6)%	(15.5)%
Valuation allowance	(5.2)%	(4.1)%	(42.2)%
Compensation-related	(1.0)%	(2.5)%	6.4 %
Non-deductible expenses	0.3 %	2.2 %	6.6 %
Uncertain tax positions	(22.0)%	10.7 %	49.5 %
TCJA net impact	(4.7)%	91.4 %	— %
Other, net	1.8 %	(0.2)%	(3.5)%
	(17.5)%	**88.8 %**	**(95.9)%**

(1) Due to the inclusion of new tax provisions in 2018 created by the TJCA, we have reclassified select items in prior years to align with the new categories established in 2018, domestic taxes on foreign earnings and uncertain tax positions.

Significant components of our deferred tax assets and liabilities are as follows:

	As of December 31,	
(in millions)	**2018**	**2017**
Deferred Tax Assets:		
Inventory costs and related reserves	$ 18	$ 29
Tax benefit of net operating loss and credits	450	478
Reserves and accruals	258	179
Restructuring-related charges	12	12
Litigation and product liability reserves	221	383
Investment write-down	28	32
Compensation related	106	104
Federal benefit of uncertain tax positions	10	163
Other	37	48
	1,140	1,428
Less: valuation allowance	(344)	(465)
	796	963
Deferred Tax Liabilities:		
Property, plant and equipment	25	33
Unrealized gains and losses on derivative financial instruments	44	5
Intangible assets	968	1,028
	1,037	1,066
Net Deferred Tax Assets / (Liabilities)	(241)	(103)
Prepaid on intercompany profit	161	66
Net Deferred Tax Assets / (Liabilities) and Prepaid on Intercompany Profit	**$ (80)**	**$ (37)**

Our deferred tax assets, deferred tax liabilities and prepaid on intercompany profit, are included in the following locations within our accompanying consolidated balance sheets (in millions):

		As of December 31,	
Component	**Location on Consolidated Balance Sheets**	**2018**	**2017**
Prepaid on intercompany profit	Prepaid income taxes	$ 161	$ 66
Non-current deferred tax asset	Other long-term assets	87	88
Deferred Tax Assets and Prepaid on Intercompany Profit		249	154
Non-current deferred tax liability	Deferred income taxes	328	191
Deferred Tax Liabilities		328	191

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Net Deferred Tax Assets (Liabilities) and Prepaid on Intercompany Profit	**$ (80)**	**$ (37)**

As of December 31, 2018, we had U.S. federal and state tax net operating loss carryforwards and tax credits, the tax effect of which was $416 million. As of December 31, 2017, we had U.S. federal and state tax net operating loss carryforwards and tax credits, the tax effect of which was $338 million. In addition, we had foreign tax net operating loss carryforwards and tax credits, the tax effect of which was $42 million as of December 31, 2018, as compared to $149 million as of December 31, 2017. These tax attributes will expire periodically beginning in 2019.

After consideration of all positive and negative evidence, we believe that it is more likely than not that a portion of our deferred tax assets will not be realized. As a result, we established a valuation allowance of $344 million as of December 31, 2018 and $465 million as of December 31, 2017, representing a decrease of $121 million. The decrease in the valuation allowance as of December 31, 2018, as compared to December 31, 2017, is primarily attributable to the release of valuation allowances against expiring net operation losses and utilization of deferred tax assets. The income tax impact of the unrealized gain or loss component of other comprehensive income and stockholders' equity was a charge of $37 million in 2018, a benefit of $63 million in 2017 and a charge of $9 million in 2016.

We obtain tax incentives through Free Trade Zone Regime offered in Costa Rica which allows 100.0 percent exemption from income tax in the first eight years of operations and 50.0 percent exemption in the following four years. This tax incentive resulted in income tax savings of $146 million for 2018, $127 million for 2017 and $123 million for 2016. The tax incentive for 100.0 percent exemption from income tax is expected to expire in 2023. The impact on per share earnings was $0.10 for 2018 and $0.09 for both 2017 and 2016. Additionally, we benefit from tax incentives in Puerto Rico. The income tax savings from Puerto Rico were immaterial for 2018, 2017 and 2016.

As of December 31, 2018, we had $427 million of gross unrecognized tax benefits, of which a net $332 million, if recognized, would affect our effective tax rate. As of December 31, 2017, we had $1.238 billion of gross unrecognized tax benefits, of which a net $1.150 billion, if recognized, would affect our effective tax rate. As of December 31, 2016, we had $1.095 billion of gross unrecognized tax benefits, of which a net $1.006 billion, if recognized, would affect our effective tax rate. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	Year Ended December 31,		
(in millions)	**2018**	**2017**	**2016**
Beginning Balance	**$ 1,238**	**$ 1,095**	**$ 1,056**
Additions based on positions related to the current year	79	134	47
Additions based on positions related to prior years	4	16	14
Reductions for tax positions of prior years	(433)	(3)	(17)
Settlements with taxing authorities	(459)	(2)	(3)
Statute of limitation expirations	(3)	(2)	(2)
Ending Balance	**$ 427**	**$ 1,238**	**$ 1,095**

We are subject to U.S. Federal income tax as well as income tax of multiple state and foreign jurisdictions. We have concluded all U.S. federal income tax matters through 2013, with the exception of select issues in 2011 and substantially all material state and local income tax matters through 2010. We have concluded all foreign income tax matters through 2013, with the exception of issues for Italy, which have concluded through 2002.

During 2010 and 2011, we received Notices of Deficiency from the Internal Revenue Service (IRS) reflecting proposed audit adjustments for Guidant Corporation (Guidant) for its 2001 through 2006 tax years and our 2006 and 2007 tax years. The total incremental tax liability asserted by the IRS for the applicable periods was $1.162 billion plus interest. The primary issue in dispute for all years was the transfer pricing associated with the technology license agreements between domestic and foreign subsidiaries of Guidant. In addition, the IRS proposed adjustments in connection with the financial terms of our Transaction Agreement with Abbott Laboratories pertaining to the sale of Guidant's vascular intervention business to Abbott Laboratories in April 2006. During 2014, we received a Revenue Agent Report (RAR) from the IRS reflecting significant proposed audit adjustments to our 2008, 2009 and 2010 tax years based upon the same transfer pricing methodologies that the IRS applied to our 2001 through 2007 tax years.

We contested in U.S. Tax Court the proposed adjustments from the IRS for Guidant for its 2001 through 2006 tax years and our 2006 and 2007 tax years related to its audit of our transfer pricing methodologies. During 2016, we entered a Stipulation of Settled Issues with the IRS intended to resolve all of the aforementioned transfer pricing issues, as well as issues related to our 2006 transaction with Abbott Laboratories. This stipulation was contingent upon the IRS Office of Appeals applying the same basis of settlement to all transfer pricing issues for the 2008 through 2010 tax years.

In the second quarter of 2018, a decision was entered by the U.S. Tax Court resolving all disputes related to the transfer pricing issues for Guidant for its 2001 through 2006 tax years and our 2006 and 2007 tax years as well as the tax issues related to our 2006 transaction with Abbott Laboratories. Additionally, we resolved all issues with the IRS Office of Appeals for our 2008 through 2010 tax years, including the transfer pricing issue and other unrelated issues. The final settlement calculation included certain elections made in these relevant years and resulted in a final net tax payment of $303 million plus $307 million of estimated interest, which was remitted in the second quarter of 2018. Due to the final settlement of these disputes, we recorded a net tax benefit of $250 million in 2018.

In the fourth quarter of 2018, we received a RAR from the IRS for our 2011 through 2013 tax years. The RAR reflected transfer pricing adjustments consistent with the basis of settlement for all transfer pricing issues agreed to in the Stipulation of Settled Issues. We remitted $93 million to the IRS in the fourth quarter of 2018 reflecting the net balance of tax and interest due for these years after consideration of amounts owed to us by the IRS. Due to the resolution of these tax years, we recorded a net tax benefit of $90 million.

We recognize interest and penalties related to income taxes as a component of income tax expense. We had $11 million accrued for gross interest and penalties as of December 31, 2018 and $655 million as of December 31, 2017. The decrease in gross interest and penalties of $643 million was recognized in our consolidated statements of operations and is primarily related to reaching settlements with the taxing authorities. We recognized net tax benefit related to interest and penalties of $498 million in 2018, as compared to a net tax expense of $154 million in 2017 and $46 million in 2016. The decrease in our net tax expense related to interest and penalties as of December 31, 2018, as compared to December 31, 2017, is related to reaching settlements with the taxing authorities.

It is reasonably possible that within the next 12 months we will resolve transactional- related issues with foreign and state taxing authorities, in which case we could record a reduction in our balance of unrecognized tax benefits of up to approximately $11 million.

There are a number of key provisions under the TCJA, which was enacted on December 22, 2017, that impact us. The final impact of the TCJA, as described below, differs from the estimates reported at December 31, 2017 due to, among other things, additional guidance issued by the U.S. Department of the Treasury, changes in interpretations and assumptions made by us, and actions that we may take as a result. The key changes from the TCJA that are reported as of December 31, 2018 are the impact due to the reduced U.S. Federal corporate tax rate from 35.0 percent to 21.0 percent and a one-time transition tax on certain foreign earnings on which U.S. income tax is deferred. As a result of finalizing the impact of the TCJA, we recognized a tax benefit of $67 million in 2018. We recognized a total TCJA related tax expense of $793 million as of December 31, 2018 as compared to the provisional estimate of $861 million recognized as of December 31, 2017.

We are required to record deferred tax assets and liabilities based on the enacted tax rates at which they are expected to reverse in the future. Therefore, any U.S. related deferred taxes were re-measured from 35.0 percent down to 21.0 percent based on the recorded balances. The analysis included an assessment on the deductibility of certain amounts for which deferred tax assets may have been recorded. As of December 31, 2017, we recorded an estimate related to the re-measurement of our deferred tax balances, which was a benefit of approximately $99 million. In 2018, we finalized our calculations and did not adjust our estimate as recorded.

We are required to calculate a one-time transition tax based on our total post-1986 foreign subsidiaries' earnings and profits (E&P) that we previously deferred from U.S. income taxes. As a result of settling our various tax audits, the revised amount of transition tax is approximately $856 million as of December 31, 2018 as compared to the preliminary amount recorded of approximately $1.044 billion as of December 31, 2017. We anticipate offsetting this liability against existing tax attributes reducing the required payment to approximately $499 million, which will be remitted over an eight-year period. We remitted the first estimated installment payment in the second quarter of 2018, with the balance remaining of $429 million as of December 31, 2018. In addition, we have provided for tax expense of $18 million on U.S. state income taxes on all U.S. dollar-denominated E&P accumulated through December 31, 2017, which constitutes the preponderance of our foreign subsidiaries' accumulated E&P through December 31, 2017. We intend to indefinitely reinvest any remaining foreign earnings as of December 31, 2017 as well as current earnings in foreign operations for which income taxes have not already been provided at December 31, 2018. Determining the amount of unrecognized deferred tax liability related to any remaining undistributed foreign earnings and additional outside basis difference in these entities is not practicable.

We are subject to a territorial tax system under the TCJA, in which we are required to provide for tax on Global Intangible Low Taxed Income (GILTI) earned by certain foreign subsidiaries. We have established an accounting policy election to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense.

NOTE J – COMMITMENTS AND CONTINGENCIES

The medical device market in which we primarily participate is largely technology driven. As a result, intellectual property rights, particularly patents and trade secrets, play a significant role in product development and differentiation. Over the years, there has been litigation initiated against us by others, including our competitors, claiming that our current or former product offerings infringe patents owned or licensed by them. Intellectual property litigation is inherently complex and unpredictable. In addition, competing parties frequently file multiple suits to leverage patent portfolios across product lines, technologies and geographies and to balance risk and exposure between the parties. In some cases, several competitors are parties in the same proceeding, or in a series of related proceedings, or litigate multiple features of a single class of devices. These forces frequently drive settlement not only for individual cases, but also for a series of pending and potentially related and unrelated cases. Although monetary and injunctive relief is typically sought, remedies and restitution are generally not determined until the conclusion of the trial court proceedings and can be modified on appeal. Accordingly, the outcomes of individual cases are difficult to time, predict or quantify and are often dependent upon the outcomes of other cases in other geographies.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

During recent years, we successfully negotiated closure of several long-standing legal matters and have received favorable rulings in several other matters; however, there continues to be outstanding intellectual property litigation. Adverse outcomes in one or more of these matters could have a material adverse effect on our ability to sell certain products and on our operating margins, financial position, results of operations and/or liquidity.

In the normal course of business, product liability, securities and commercial claims are asserted against us. Similar claims may be asserted against us in the future related to events not known to management at the present time. We maintain an insurance policy providing limited coverage against securities claims and we are substantially self-insured with respect to product liability claims and fully self-insured with respect to intellectual property infringement claims. The absence of significant third-party insurance coverage increases our potential exposure to unanticipated claims or adverse decisions. Product liability claims, securities and commercial litigation and other legal proceedings in the future, regardless of their outcome, could have a material adverse effect on our financial position, results of operations and/or liquidity.

In addition, like other companies in the medical device industry, we are subject to extensive regulation by national, state and local government agencies in the U.S. and other countries in which we operate. From time to time we are the subject of qui tam actions and governmental investigations often involving regulatory, marketing and other business practices. These qui tam actions and governmental investigations could result in the commencement of civil and criminal proceedings, substantial fines, penalties and administrative remedies and have a material adverse effect on our financial position, results of operations and/or liquidity.

In accordance with FASB ASC Topic 450, *Contingencies*, we accrue anticipated costs of settlement, damages, losses for product liability claims and, under certain conditions, costs of defense, based on historical experience or to the extent specific losses are probable and estimable. Otherwise, we expense these costs as incurred. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue the minimum amount of the range.

Our accrual for legal matters that are probable and estimable was $929 million as of December 31, 2018 and $1.612 billion as of December 31, 2017 and includes certain estimated costs of settlement, damages and defense. The decrease in our legal accrual was primarily due to settlement payments authorized in 2018 associated with product liability cases or claims related to transvaginal surgical mesh products. A portion of our legal accrual is funded and included in our restricted cash and restricted cash equivalent balances in *Other current assets* of $655 million as of December 31, 2018 and $803 million as of December 31, 2017, as discussed in *Note A – Significant Accounting Policies*. We recorded litigation-related net charges in the amount of $103 million in 2018, $285 million in 2017 and $804 million in 2016. We continue to assess certain litigation and claims to determine the amounts, if any, that management believes will be paid as a result of such claims and litigation and, therefore, additional losses may be accrued and paid in the future, which could materially adversely impact our operating results, cash flows and/or our ability to comply with our debt covenants.

In management's opinion, we are not currently involved in any legal proceedings other than those specifically identified below, which, individually or in the aggregate, could have a material adverse effect on our financial condition, operations and/or cash flows. Unless included in our legal accrual or otherwise indicated below, a range of loss associated with any individual material legal proceeding cannot be estimated.

Patent Litigation

On November 29, 2016 Nevro Corp. (Nevro) filed a patent infringement action against us and one of our subsidiaries, Boston Scientific Neuromodulation Corporation, in the U.S. District Court for the Northern District of California alleging that six U.S. patents (Alataris) owned by Nevro are infringed by our spinal cord stimulation systems. On June 29, 2017, Nevro amended the complaint to add an additional patent (Fang). We deny the plaintiff's allegations and intend to defend ourselves vigorously. On July 24, 2018, summary judgment was entered in favor of the Company and on July 31, 2018, we received final judgment and dismissal of the action. On July 31, 2018, Nevro filed an appeal.

On December 9, 2016, the Company and Boston Scientific Neuromodulation Corporation filed a patent infringement action against Nevro in U.S. District Court for the District of Delaware alleging that ten U.S. patents owned by Boston Scientific Neuromodulation Corporation are infringed by Nevro's Senza™ Spinal Cord Stimulation System.

On March 10, 2017, Imran Niazi filed a patent infringement action against us in the U.S. District Court for the Western District of Wisconsin alleging that a U.S. patent owned by him is infringed by our Acuity™ Lead Delivery System. On June 30, 2017, we filed a motion to dismiss for improper venue and on November 7, 2017 the Wisconsin Court granted the motion to dismiss. On November 13, 2017 Niazi refiled the same action in the U.S. District of Minnesota.

On November 20, 2017, The Board of Regents, University of Texas System (UT) and TissueGen. Inc., served a lawsuit against us in the Western District of Texas. The complaint against us alleges patent infringement of two U.S. patents owned by UT, relating to "Drug Releasing Biodegradable Fiber Implant" and "Drug Releasing Biodegradable Fiber for Delivery of Therapeutics," and affects the manufacture, use and sale of our Synergy™ Stent System. On March 12, 2018, the court dismissed the action and transferred it to the United States District Court for the District of Delaware. UT has appealed the decision.

On April 21, 2018, the Company and Boston Scientific Neuromodulation Corporation filed a patent infringement, theft of trade secrets and tortious interference with a contract action against Nevro in U.S. District Court for the District of Delaware, and amended the complaint on July 18, 2018, alleging that nine U.S. patents owned by Boston Scientific Neuromodulation Corporation are infringed by Nevro's Senza™ I and Senza™ II Spinal Cord Stimulation Systems.

Product Liability Litigation

No individual lawsuits remain pending in state court jurisdictions against Guidant alleging personal injuries associated with defibrillators or pacemakers involved in certain 2005 and 2006 product communications. Further, we are aware of approximately six Guidant product liability lawsuits pending in international jurisdictions associated with defibrillators or pacemakers, including devices involved in the 2005 and 2006 product communications. Four of these suits are pending in Canada involving certain models of Guidant pacemakers, three of which are stayed pending the outcome of one lead class action. On May 8, 2009, the Justice of Ontario Court certified a class of persons in whom pacemakers were implanted in Canada and a class of family members with derivative claims. In each case, these matters generally seek monetary damages from us. This class action has been inactive since 2011. On March 24, 2014, the Ontario Superior Court approved a $3 million settlement of a class action involving certain models of Guidant defibrillators. We believe Guidant has satisfied its obligations pursuant to the settlement agreement.

As of February 5, 2019, approximately 53,000 product liability cases or claims related to transvaginal surgical mesh products designed to treat stress urinary incontinence and pelvic organ prolapse have been asserted against us. The pending cases are in various federal and state courts in the U.S. and include eight putative class actions. There were also fewer than 25 cases in Canada, inclusive of one certified and three putative class actions and fewer than 25 claims in the United Kingdom. Generally, the plaintiffs allege personal injury associated with use of our transvaginal surgical mesh products. The plaintiffs assert design and manufacturing claims, failure to warn, breach of warranty, fraud, violations of state consumer protection laws and loss of consortium claims. Over 3,100 of the cases have been specially assigned to one judge in state court in Massachusetts. On February 7, 2012, the Judicial Panel on Multi-District Litigation (MDL) established MDL-2326 in the U.S. District Court for the Southern District of West Virginia and transferred the federal court transvaginal surgical mesh cases to MDL-2326 for coordinated pretrial proceedings. During the fourth quarter of 2013, we received written discovery requests from certain state attorneys general offices regarding our transvaginal surgical mesh products. We have responded to those requests. As of February 5, 2019, we have entered into master settlement agreements in principle or are in the final stages of entering one with certain plaintiffs' counsel to resolve an aggregate of approximately 50,000 cases and claims. These master settlement agreements provide that the settlement and distribution of settlement funds to participating claimants are conditional upon, among other things, achieving minimum required claimant participation thresholds. Of the approximately 50,000 cases and claims, approximately 35,500 have met the conditions of the settlement and are final. All settlement agreements were entered into solely by way of compromise and without any admission or concession by us of any liability or wrongdoing.

On or about January 12, 2016, Teresa L. Stevens filed a claim against us and three other defendants asserting for herself and on behalf of a putative class of similarly situated women, that she was harmed by a vaginal mesh implant that she alleges contained a counterfeit or adulterated resin product that we imported from China. The complaint was filed in the U.S. District Court for the Southern District of West Virginia, before the same Court that is hearing the mesh MDL. The complaint, which alleges Racketeer Influenced and Corrupt Organizations Act (RICO) violations, fraud, misrepresentation, deceptive trade practices and unjust enrichment, seeks both equitable relief and damages under state and federal law. On January 26, 2016, the Court issued an order staying the case and directing the plaintiff to submit information to allow the FDA to issue a determination with respect to her allegations. In addition, we are in contact with the U.S. Attorney's Office for the Southern District of West Virginia and are responding voluntarily to their requests in connection with that office's review of the allegations concerning the use of mesh resin in the complaint. We deny the plaintiff's allegations and intend to defend ourselves vigorously.

On February 27, 2017, Carolyn Turner filed a complaint against us and five other defendants asserting for herself and on behalf of a putative class of similarly situated women, that she was harmed by a vaginal mesh implant that she alleges contained a counterfeit or adulterated resin product that we imported from China. The complaint was filed in the U.S. District Court for the Middle District of Florida, Orlando Division and alleges violations of the RICO, negligence, strict liability, breach of an express or implied warranty,

intentional and negligent misrepresentation, fraud and unjust enrichment. Ms. Turner served this complaint against us on April 7, 2017. As of April 27, 2017, this case has been stayed, pending resolution of the transfer petition to the mesh multidistrict litigation. We deny the plaintiff's allegations and intend to defend ourselves vigorously.

98

We have established a product liability accrual for known and estimated future cases and claims asserted against us as well as with respect to the actions that have resulted in verdicts against us and the costs of defense thereof associated with our transvaginal surgical mesh products. While we believe that our accrual associated with this matter is adequate, changes to this accrual may be required in the future as additional information becomes available. While we continue to engage in discussions with plaintiffs' counsel regarding potential resolution of pending cases and claims and intend to vigorously contest the cases and claims asserted against us, that do not settle, the final resolution of the cases and claims is uncertain and could have a material impact on our results of operations, financial condition and/or liquidity. Initial trials involving our transvaginal surgical mesh products have resulted in both favorable and unfavorable judgments for us. We do not believe that the judgment in any one trial is representative of potential outcomes of all cases or claims related to our transvaginal surgical mesh products.

Governmental Investigations and Qui Tam Matters

On August 3, 2012, we were served with a qui tam complaint that had previously been filed under seal against Boston Scientific Neuromodulation Corporation in the U.S. District Court for the District of New Jersey on March 2, 2011. On August 8, 2012, we learned that the federal government had previously declined to intervene in this matter. The relators' complaint, now unsealed, alleges that Boston Scientific Neuromodulation Corporation violated the federal and various states' false claims acts through submission of fraudulent bills for implanted devices, under-reporting of certain adverse events and promotion of off-label uses. On September 10, 2012, the relators filed an amended complaint revising and restating certain of the claims in the original complaint. Our motion to dismiss, filed subsequently, was denied on May 31, 2013 and on June 28, 2013, we answered the amended complaint and brought certain counterclaims arising from relators' unauthorized removal of documents from the business during their employments, which the relators moved to dismiss on July 22, 2013. The Court denied relators' motion to dismiss the counterclaims on September 4, 2014. Following the completion of fact and expert discovery, we filed a motion for summary judgment against all claims on January 27, 2017, relators filed their own motion for summary judgment against our counterclaims that same date and the parties await the Court's rulings on the motions. On December 15, 2017, the Court denied both motions for summary judgment. The case is set for trial beginning May 6, 2019.

On May 5, 2014, we were served with a subpoena from the U.S. Department of Health and Human Services, Office of the Inspector General. The subpoena seeks information relating to the launch of the Cognis™ and Teligen™ line of devices in 2008, the performance of those devices from 2007 to 2009 and the operation of the Physician Guided Learning Program. We are cooperating with this request. On May 6, 2016, a qui tam lawsuit in this matter was unsealed in the U.S. District Court for the District of Minnesota. At the same time, we learned that the U.S. government and the State of California had earlier declined to intervene in that lawsuit on April 15, 2016. The complaint was served on us on July 21, 2016. On October 7, 2016, the plaintiff/relator served an amended complaint that dropped the allegations relating to the Physician Guided Learning Program. We filed a motion to dismiss the amended complaint on December 7, 2016 and the court heard our motion to dismiss on April 5, 2017. On August 29, 2017, the Court granted the motion to dismiss, without prejudice and on September 19, 2017, the relator filed a Second Amended Complaint. We filed a motion to dismiss the Second Amended Complaint on October 10, 2017 and the Court denied that motion on December 13, 2017. On July 31, 2018, relator filed a motion seeking leave to file a Third Amended Complaint. The Court denied the motion on October 30, 2018.

On February 23, 2015, a judge for the Court of Modena (Italy) ordered a trial for Boston Scientific SpA and three of its employees, as well as numerous other defendants charged in criminal proceedings. The charges arise from allegations that the defendants made improper donations to certain health care providers and other employees of the Hospital of Modena in order to induce them to conduct unauthorized clinical trials, as well as related government fraud in relation to the financing of such clinical trials. A trial began on February 24, 2016 and is ongoing. On November 10, 2017, the Court issued a ruling that convicted one Boston Scientific employee but acquitted two others, and levied a fine of €245 thousand against us and imposed joint and several civil damages of €620 thousand on all defendants. We continue to deny these allegations, timely appealed the decision on May 10, 2018 and intend to continue to defend ourselves vigorously.

On December 1, 2015, the Brazilian governmental entity known as CADE (the Administrative Council of Economic Defense), served a search warrant on the offices of our Brazilian subsidiary, as well as on the Brazilian offices of several other major medical device makers who do business in Brazil, in furtherance of an investigation into alleged anti-competitive activity with respect to certain tender offers for government contracts. On June 20, 2017, CADE, through the publication of a "technical note," announced that it was launching a formal administrative proceeding against Boston Scientific's Brazilian subsidiary, Boston Scientific do Brasil Ltda., as well as against the Brazilian operations of Medtronic, Biotronik and St. Jude Medical, two Brazilian associations, ABIMED and AMBIMO and 29 individuals for alleged anti-competitive behavior. We deny the allegations and intend to defend ourselves vigorously.

On December 14, 2016, we learned that the Associacao Brasileira de Medicina de Grupo d/b/a ABRAMGE filed a complaint against us, Arthrex and Zimmer Biomet Holdings, in the U.S. District Court for the District of Delaware. This complaint, which ABRAMGE never served against us, alleges that the defendants or their agents paid kickbacks to health care providers in order to increase sales and prices and are liable under a variety of common law theories. On February 6, 2017, ABRAMGE filed and served an amended complaint on us and the other defendants. The amended complaint does not contain any material changes in the allegations against us. Subsequently, on March 2, 2017, ABRAMGE filed a motion to consolidate this lawsuit with two other similar suits that it had brought against Stryker and Abbott Laboratories, in a multidistrict litigation proceeding. On April 13, 2017, we filed a motion to dismiss the amended complaint, as well as a separate opposition to the multidistrict litigation motion and on May 31, 2017, the Joint Panel on Multi-District Litigation denied ABRAMGE's motion for the multidistrict litigation. On September 1, 2017, ABRAMGE filed a motion for leave to file a Second Amended Complaint, while our motion to dismiss the Amended Complaint remained pending. On September 15, 2017, we filed an opposition to the motion seeking leave to amend. Both our motion to dismiss and the motion seeking leave to amend remain pending. On November 8, 2018, the Court granted ABRAMGE's motion for leave to file a Second Amended Complaint, while also granting us leave to renew our motion to dismiss. We filed our motion to dismiss the Second Amended Complaint on January 18, 2019.

Other Proceedings

On May 16, 2018, Arthur Rosenthal et al., filed a plenary summons against Boston Scientific Corporation and Boston Scientific Limited with the High Court of Ireland alleging that payments are due pursuant a transaction agreement regarding Labcoat Limited.

On September 12, 2018, Channel Medsystems, Inc. (Channel) filed a complaint in Delaware Chancery Court against us for alleged breach of a $275 million purchase agreement. Channel alleges that we breached the agreement by terminating it. We have answered the complaint, denied the claims by Channel and have counterclaimed to recover part of our investment in Channel, alleging fraud in the inducement. The court has set a trial date of April 15, 2019.

Refer to *Note I - Income Taxes* for information regarding our tax litigation.

Proposed Acquisition

Refer to *Note B – Acquisitions and Strategic Investments* and *Note E – Borrowings and Credit Arrangements* for information regarding the proposed BTG Acquisition.

Matters Concluded Since December 31, 2017

On October 28, 2016, the Regents of the University of California filed a patent infringement action against us in the U.S. District Court for the Northern District of California alleging that two U.S. patents (Lesh) owned by the Regents of the University of California are infringed by certain of our catheters and other devices used to treat atrial fibrillation. The Company and the Regents settled the matter, and the case was dismissed on June 20, 2018.

On May 19, 2005, G. David Jang, M.D. filed suit against us alleging breach of contract relating to certain patent rights covering stent technology. The suit was filed in the U.S. District Court for the Central District of California seeking monetary damages and rescission of contract. After a Markman ruling relating to the Jang patent rights, Dr. Jang stipulated to the dismissal of certain claims alleged in the complaint with a right to appeal and the parties subsequently agreed to settle the other claims. In May 2007, Dr. Jang filed an appeal with respect to the remaining patent claims and in July 2008, the Court of Appeals vacated the District Court's consent judgment and remanded the case back to the District Court for further clarification. In August 2011, the District Court entered a stipulated judgment that we did not infringe the Jang patent. Dr. Jang filed an appeal on September 21, 2011 and on August 22, 2012, the Court of Appeals vacated the District Court's judgment and remanded the case to the District Court for further proceedings. On July 8, 2015, a jury found that our Express™ Stent family did not literally infringe a Jang patent, but that the stents infringed under the doctrine of equivalents. The court reserved judgment until the conclusion of further proceedings related to the doctrine of equivalents finding. On September 29, 2015, the court ruled that our Express Stent family did not infringe under the doctrine of equivalents and, on October 30, 2015, the court entered judgment in our favor. On November 25, 2015, Dr. Jang filed a motion for judgment as a matter of law on literal infringement and/or for a new trial. On February 3, 2016, the court denied Dr. Jang's motion for a new trial and judgment as a matter of law. Dr. Jang filed a notice of appeal. On September 29, 2017, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment that our Express Stent did not infringe the Jang patents and we did not owe Dr. Jang any payments. On October 30, 2017, Jang filed a petition for rehearing and on December 21, 2017 the rehearing was denied. On March 21, 2018, Jang filed a petition for United States Supreme Court review and, on October 1, 2018, the Supreme Court denied his petition.

On January 15, 2019, we announced that we reached an agreement with Edwards Lifesciences Corporation (Edwards) to settle all outstanding patent disputes between us and Edwards in all venues around the world. All pending cases or appeals in courts and patent offices between the two companies will be dismissed, and the parties will not litigate patent disputes related to current portfolios of transcatheter aortic valves, certain mitral valve repair devices, and left atrial appendage closure devices. Any injunctions currently in place will be lifted. Under the terms of the agreement, Edwards made a one-time payment to us of $180 million. No further royalties will be owed by either party under the agreement. All other terms remain confidential. The previously disclosed matters that have been resolved as a result of this settlement include:

- On October 30, 2015, a subsidiary of Boston Scientific filed suit against Edwards Lifesciences Corporation and Edwards Lifesciences Services GmbH in Düsseldorf District Court in Germany for patent infringement. We allege that Edwards' SAPIEN 3™ Heart Valve infringes our patent related to adaptive sealing technology. On February 25, 2016, we extended the action to allege infringement of a second patent related to adaptive sealing technology. The trial began on February 7, 2017. On March 9, 2017, the court found that Edwards infringed both patents and Edwards appealed.

- On November 9, 2015, Edwards Lifesciences, LLC filed an invalidity claim against one of our subsidiaries, Sadra Medical, Inc. (Sadra), in the High Court of Justice, Chancery Division Patents Court in the United Kingdom, alleging that a European patent owned by Sadra relating to a repositionable heart valve is invalid. On January 15, 2016, we filed our defense and counterclaim for a declaration that our European patent is valid and infringed by Edwards. On February 25, 2016, we amended our counterclaim to allege infringement of a second patent related to adaptive sealing technology. A trial was held from January 18 to January 27, 2017. On March 3, 2017, the court found one of our patents valid and infringed and some claims of the second patent invalid and the remaining claims not infringed. Both parties have filed an appeal. On March 28, 2018, the Court of Appeals affirmed the decision of the High Court.

- On November 23, 2015, Edwards Lifesciences PVT, Inc. filed a patent infringement action against us and one of our subsidiaries, Boston Scientific Medizintechnik GmbH, in the District Court of Düsseldorf, Germany alleging a European patent (Spenser '672) owned by Edwards is infringed by our Lotus™ Valve System. The trial began on February 7, 2017. On March 9, 2017, the court found that we did not infringe the Spenser '672 patent. Edwards filed an appeal.

- On November 23, 2015, Edwards Lifesciences Corporation filed a patent infringement action against us and Boston Scientific Medizintechnik GmbH in the District Court of Düsseldorf, Germany alleging an European patent (Bourang) owned by Edwards is infringed by our Lotus Valve System. The trial began on February 7, 2017. On March 28, 2017, the European Patent Office revoked the Bourang patent and on April 3, 2017, the court suspended the infringement action pending Edwards' appeal of the revocation of the patent at the European Patent Office.

- On April 19, 2016, a subsidiary of Boston Scientific filed suit against Edwards Lifesciences Corporation (Edwards) in the U.S. District Court for the District of Delaware for patent infringement. We allege that Edwards' SAPIEN 3 Valve infringes a patent related to adaptive sealing technology. On June 9, 2016, Edwards filed a counterclaim alleging that our Lotus Valve System infringes three patents owned by Edwards. On October 12, 2016, Edwards filed a petition for inter partes review of our patent with the U.S. Patent and Trademark Office (USPTO), Patent Trial and Appeal Board. On March 29, 2017, the USPTO granted the inter partes review request. On April 18, 2017, Edwards filed a second petition for inter partes review of our patent with the USPTO. On March 23, 2018, the USPTO found our patent invalid. The Company filed an appeal before the United States Court of Appeals for the Federal Circuit on May 24, 2018.

- On April 19, 2016, a subsidiary of Boston Scientific filed suit against Edwards Lifesciences Corporation in the U.S. District Court for the Central District of California for patent infringement. We allege that Edwards' aortic valve delivery systems infringe eight of our catheter related patents. On October 13, 2016, Edwards filed a petition for inter partes review of one asserted patent with the USPTO, Patent Trial and Appeal Board. On April 21, 2017, the USPTO denied the petition. On April 19 and 20, 2017, Edwards filed multiple inter partes review petitions against the patents in suit. On September 8, 2017, the court granted a stay of the action pending an inter partes review of the patents in suit.

- On April 26, 2016, Edwards Lifesciences PVT, Inc. filed a patent infringement action against us and one of our subsidiaries, Boston Scientific Medizintechnik GmbH, in the District Court of Düsseldorf, Germany alleging a European patent (Spenser '550) owned by Edwards is infringed by our Lotus Transcatheter Heart Valve System. The trial began on February 7, 2017. On March 9, 2017, the court found that we infringed the Spenser '550 patent. The Company filed an appeal. The appeal hearing is scheduled for May 17, 2018. On April 13, 2018, the '550 patent was revoked by the European Patent Office.

- On October 27, 2016, Edwards Lifesciences PVT, Inc. filed a patent infringement action against us and one of our subsidiaries, Boston Scientific, LTD, in the Federal Court of Canada alleging that three Canadian patents (Spenser) owned by Edwards are infringed by our Lotus Transcatheter Heart Valve System.

- On December 22, 2016, Edwards Lifesciences PVT, Inc. and Edwards Lifesciences SA (AG) filed a plenary summons against Boston Scientific Limited and Boston Scientific Group Public Company in the High Court of Ireland alleging that a European patent (Spenser) owned by Edwards is infringed by our Lotus Valve System. On April 13, 2018, the '550 patent was revoked by the European Patent Office.

- On August 1, 2018, the Company filed a patent infringement action on the merits in Dusseldorf, Germany against Edwards Lifesciences Corporation and Edwards Lifesciences GmbH (collectively Edwards) alleging that the Sapien 3™ device and Sapien 3 Ultra device infringed a patent owned by the Company.

- On August 3, 2018, the Company filed a preliminary injunction request in Dusseldorf, Germany against Edwards Lifesciences Corporation and Edwards Lifesciences GmbH (collectively Edwards) alleging that the Sapien 3 Ultra infringed a patent owned by the Company. On October 23, 2018, the court found that the Sapien 3 Ultra infringed the patent. Edwards had the right to appeal.

- On August 22, 2018, Edwards Lifesciences LLC filed a patent infringement action against Boston Scientific Corporation, in the U. S. District Court of Delaware, alleging that two U.S. patents (Schweich) owned by them are infringed by our Watchman™ Left Atrial Appendage Closure Device, Watchman Delivery System and Watchman Access System.

NOTE K – STOCKHOLDERS' EQUITY

Preferred Stock

We are authorized to issue 50 million shares of preferred stock in one or more series and to fix the powers, designations, preferences and relative participating, option or other rights thereof, including dividend rights, conversion rights, voting rights, redemption terms, liquidation preferences and the number of shares constituting any series, without any further vote or action by our stockholders. As of December 31, 2018 and 2017, we had no shares of preferred stock issued or outstanding.

Common Stock

We are authorized to issue 2.000 billion shares of common stock, $0.01 par value per share. Holders of common stock are entitled to one vote per share. Holders of common stock are entitled to receive dividends, if and when declared by our Board of Directors and to share ratably in our assets legally available for distribution to our stockholders in the event of liquidation. Holders of common stock have no preemptive, subscription, redemption, or conversion rights. The holders of common stock do not have cumulative voting rights. The holders of a majority of the shares of common stock can elect all of the directors and can control our management and affairs.

On January 25, 2013, our Board of Directors approved a stock repurchase program authorizing the repurchase of up to $1.000 billion of our common stock. Repurchased shares are available for reissuance under our equity incentive plans and for general corporate purposes, including acquisitions. We did not repurchase any shares of our common stock during 2018, 2017 or 2016. As of December 31, 2018, we had remaining $535 million authorized under our 2013 share repurchase program. There were approximately 248 million shares in treasury as of December 31, 2018 and December 31, 2017.

NOTE L – STOCK INCENTIVE AND OWNERSHIP PLANS

Employee and Director Stock Incentive Plans

In 2011, our Board of Directors and stockholders approved our 2011 Long-Term Incentive Plan (the 2011 LTIP), authorizing for issuance up to 146 million shares of our common stock. The 2011 LTIP covers officers, directors, employees and consultants and provides for the grant of restricted or unrestricted common stock, deferred stock units (DSU), options to acquire our common stock, stock appreciation rights, performance awards (market-based and performance-based DSUs) and other stock and non-stock awards. Shares

reserved under our current and former stock incentive plans totaled approximately 132 million as of December 31, 2018. The Executive Compensation and Human Resources Committee (the Committee) of the Board of Directors, consisting of independent, non-employee directors may authorize the issuance of common stock and cash awards under the 2011 LTIP in recognition of the achievement of long-term performance objectives established by the Committee.

Non-qualified options issued to employees are generally granted with an exercise price equal to the market price of our stock on the grant date, vest over a four-year service period and have a ten-year contractual life. In the case of qualified options, if the recipient owns more than ten percent of the voting power of all classes of stock, the option granted will be at an exercise price of 110 percent of the fair market value of our common stock on the date of grant and will expire over a period not to exceed five years. Non-vested stock awards, including restricted stock awards and DSUs, issued to employees are generally granted with an exercise price of zero and typically vest in five equal annual installments. These awards represent our commitment to issue shares to recipients after the vesting period. Upon each vesting date, such awards are no longer subject to risk of forfeiture and we issue shares of our common stock to the recipient.

The following presents the impact of stock-based compensation on our consolidated statements of operations:

	Year Ended December 31,		
(in millions, except per share data)	**2018**	**2017**	**2016**
Cost of products sold	$ 7	$ 7	$ 6
Selling, general and administrative expenses	109	98	90
Research and development expenses	24	23	20
	140	127	116
Income tax (benefit) expense	(21)	(32)	(29)
	$ 119	**$ 96**	**$ 87**
Net impact per common share - basic	$ 0.09	$ 0.07	$ 0.06
Net impact per common share - assuming dilution	$ 0.08	$ 0.07	$ 0.06

Stock Options

We use the Black-Scholes option-pricing model to calculate the grant-date fair value of stock options granted to employees under our stock incentive plans. We calculated the fair value for options granted using the following estimated weighted-average assumptions:

	Year Ended December 31,		
	2018	**2017**	**2016**
Options granted *(in thousands)*	3,491	4,439	4,186
Weighted-average exercise price	$ 27.26	$ 24.70	$ 17.46
Weighted-average grant-date fair value	$ 8.55	$ 7.16	$ 5.60
Black-Scholes Assumptions			
Expected volatility	26%	25%	30%
Expected term *(in years, weighted)*	6.0	6.1	6.0
Risk-free interest rate	2.61% - 3.01%	2.03% - 2.21%	1.14% - 2.08%

Expected Volatility

We use our historical volatility and implied volatility as a basis to estimate expected volatility in our valuation of stock options.

Expected Term

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

We estimate the expected term of options using historical exercise and forfeiture data. We believe that this historical data provides the best estimate of the expected term of new option grants.

Risk-Free Interest Rate

We use yield rates on U.S. Treasury securities for a period approximating the expected term of the award to estimate the risk-free interest rate in our grant-date fair value assessment.

Expected Dividend Yield

We have not historically paid cash dividends to our stockholders and currently do not intend to pay cash dividends. Therefore, we have assumed an expected dividend yield of zero in our grant-date fair value assessment.

Information related to stock options under stock incentive plans are as follows:

	Stock Options *(in thousands)*	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life *(in years)*	Aggregate Intrinsic Value *(in millions)*
Outstanding as of December 31, 2015	**31,089**	**$ 11**		
Granted	4,186	17		
Exercised	(6,612)	12		
Cancelled/forfeited	(2,019)	21		
Outstanding as of December 31, 2016	**26,644**	**$ 11**		
Granted	4,439	25		
Exercised	(3,922)	10		
Cancelled/forfeited	(445)	17		
Outstanding as of December 31, 2017	**26,716**	**$ 13**		
Granted	3,491	27		
Exercised	(4,385)	11		
Cancelled/forfeited	(519)	22		
Outstanding as of December 31, 2018	**25,304**	**$ 16**	**5.5**	**$ 499**
Exercisable as of December 31, 2018	16,535	$ 11	4.1	$ 396
Expected to vest as of December 31, 2018	8,319	23	8.2	99
Total vested and expected to vest as of December 31, 2018	**24,854**	**$ 15**	**5.4**	**$ 495**

The total intrinsic value of stock options exercised was $90 million in 2018 and $64 million in both 2017 and 2016.

Non-Vested Stock

We value restricted stock awards and DSUs based on the closing trading value of our shares on the date of grant. Information related to non-vested stock awards is as follows:

	Non-Vested Stock Award Units *(in thousands)*	Weighted Average Grant-Date Fair Value
Balance as of December 31, 2015	**23,764**	**$ 11**
Granted	6,132	17
Vested (1)	(10,045)	10
Forfeited	(1,054)	13
Balance as of December 31, 2016	**18,797**	**$ 14**
Granted	4,798	24
Vested (1)	(7,663)	11
Forfeited	(683)	17
Balance as of December 31, 2017	**15,250**	**$ 18**
Granted	4,375	28
Vested (1)	(6,194)	16
Forfeited	(748)	22
Balance as of December 31, 2018	**12,683**	**$ 22**

(1) The number of restricted stock units vested includes shares withheld on behalf of employees to satisfy statutory tax withholding requirements.

The total vesting date fair value of stock award units that vested was approximately $170 million in 2018, $190 million in 2017 and $179 million in 2016.

Market-based DSU Awards

During 2018, 2017 and 2016, we granted market-based DSU awards to certain members of our senior management team. The number of shares ultimately issued to the recipient is based on the total shareholder return (TSR) of our common stock as compared to the TSR of the common stock of the other companies in the S&P 500 Health Care Index over a three-year performance period. The number of DSUs ultimately granted under this program range from 0 percent to 200 percent of the target number of performance-based DSUs awarded to the participant as determined by achievement of the performance criteria of the program. In addition, award recipients must remain employed by us throughout the three-year performance period to attain the full amount of the market-based DSUs that satisfied the market performance criteria.

We determined the fair value of the market-based DSU awards to be approximately $7 million for 2018, $8 million for 2017 and $6 million for 2016. We determined these fair values based on Monte Carlo simulations as of the date of grant, utilizing the following assumptions:

	2018 Awards	2017 Awards	2016 Awards
Stock price on date of grant	$ 27.09	$ 24.55	$ 17.26
Measurement period *(in years)*	2.9	2.8	2.9

Risk-free rate	2.36%	1.45%	0.90%

We recognize the expense on these awards in our consolidated statements of operations on a straight-line basis over the three-year measurement period.

Free Cash Flow Performance-based DSU Awards

During 2018, 2017 and 2016, we granted free cash flow performance-based DSU awards to certain members of our senior management team. The attainment of these performance-based DSUs is based on our adjusted free cash flow (AFCF) measured against our internal annual financial plan performance for AFCF. AFCF is measured over a one-year performance period beginning January 1st of each year and ending December 31st. The number of DSUs ultimately granted under this program range from 0 percent to 150 percent of the target number of performance-based DSUs awarded to the participant as determined by achievement of the performance criteria of the program. In addition, award recipients must remain employed by us throughout a three-year service period (inclusive of the one-year performance period) to attain the full amount of the performance-based DSUs that satisfied the performance criteria.

The following table presents our assumptions used in determining the fair value of our AFCF awards currently expected to vest as of December 31, 2018:

	2018 AFCF	2017 AFCF	2016 AFCF
Fair value, net of forfeitures to date *(in millions)*	$ 11	$ 6	$ 7
Achievement of target payout	118%	98%	114%
Year-end stock price used in determining fair value	$ 35.34	$ 24.79	$ 21.63

We recognize the expense on these awards in our consolidated statements of operations over the vesting period which is three years after the date of grant.

Expense Attribution

We recognize compensation expense for our stock incentive plan using a straight-line method over the substantive vesting period. Most of our stock awards provide for immediate vesting upon death or disability of the participant. In addition, our stock grants to employees provide for accelerated vesting of our stock-based awards, other than performance-based and market-based awards, upon retirement. In accordance with the terms of our stock grants, for employees who will become retirement eligible prior to the vest date we expense stock-based awards, other than performance-based and market-based awards, over the greater of one year or the period between grant date and retirement-eligibility. The performance-based and market-based awards discussed above do not contain provisions that would accelerate the full vesting of the awards upon retirement-eligibility.

We recognize stock-based compensation expense for the value of the portion of awards that are ultimately expected to vest. FASB ASC Topic 718, *Compensation – Stock Compensation* allows forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered stock-based award. We have applied, based on an analysis of our historical forfeitures, a weighted-average annual forfeiture rate of approximately six percent to all unvested stock-based awards as of December 31, 2018, which represents the portion that we expect will be forfeited each year over the vesting period. We re-evaluate this analysis annually or more frequently if there are significant changes in circumstances and adjust the forfeiture rate as necessary. Ultimately, we will only recognize expense for those shares that vest.

Unrecognized Compensation Cost

We expect to recognize the following future expense for awards outstanding as of December 31, 2018:

	Unrecognized Compensation Cost *(in millions)* (1)	Weighted Average Remaining Vesting Period *(in years)*
Stock options	$ 32	
Non-vested stock awards	151	

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

	$ 183	1.4

(1) Amounts presented represent compensation cost, net of estimated forfeitures.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Employee Stock Purchase Plans

Our global employee stock purchase plan provides for the granting of options to purchase up to 50 million shares of our common stock to all eligible employees. Under the global employee stock purchase plan, we grant each eligible employee, at the beginning of each six-month offering period, an option to purchase shares of our common stock equal to not more than ten percent of the employee's eligible compensation or the statutory limit under the U.S. Internal Revenue Code. Such options may be exercised only to the extent of accumulated payroll deductions at the end of the offering period, at a purchase price equal to 85 percent of the fair market value of our common stock at the beginning or end of each offering period, whichever is less. As of December 31, 2018, there were approximately 10 million shares available for future issuance under the employee stock purchase plan.

Information related to shares issued or to be issued in connection with the employee stock purchase plan based on employee contributions and the range of purchase prices is as follows:

	Year Ended December 31,		
	2018	**2017**	**2016**
Shares issued or to be issued *(in thousands)*	2,452	2,491	2,337
Range of purchase prices	$21.49 - $27.91	$18.60 - $21.07	$15.29 - $18.39
Expense recognized *(in millions)*	$ 17	$ 13	$ 11

We use the Black-Scholes option-pricing model to calculate the grant-date fair value of shares issued under the employee stock purchase plan. We recognize expense related to shares purchased through the employee stock purchase plan ratably over the offering period.

NOTE M – WEIGHTED AVERAGE SHARES OUTSTANDING

	Year Ended December 31,		
(in millions)	**2018**	**2017**	**2016**
Weighted average shares outstanding - basic	1,381.0	1,370.1	1,357.6
Net effect of common stock equivalents	20.4	22.6	19.6
Weighted average shares outstanding - assuming dilution	**1,401.4**	**1,392.7**	**1,377.2**

The impact of stock options outstanding with exercise prices greater than the average fair market value of our common stock was immaterial for all periods presented.

NOTE N – SEGMENT REPORTING

We have three reportable segments comprised of MedSurg, Rhythm and Neuro, and Cardiovascular, which represent an aggregation of our operating segments.

Each of our reportable segments generates revenues from the sale of medical devices. We measure and evaluate our reportable segments based on segment net sales and operating income, excluding intersegment profits. In 2017, we updated our presentation of segment net sales and operating income to include the impact of foreign currency fluctuations, since our chief operating decision maker (CODM) reviews operating results both including and excluding the impact of foreign currency fluctuations, and the following presentation more closely aligns to our consolidated financial statements. We exclude from segment operating income certain corporate-related expenses and certain transactions or adjustments that our CODM considers to be non-operational, such as amounts related to amortization expense, intangible asset impairment charges, acquisition-related items, restructuring and restructuring-related items and litigation-related items. Although we exclude these amounts from segment operating income, they are included in reported *Income (loss) before income taxes* on the consolidated statements of operations and are included in the reconciliation below.

Effective January 1, 2018, following organizational changes to align the structure of our business with our focus on active implantable devices, we revised our reportable segments, in accordance with FASB ASC Topic 280, *Segment Reporting*. The revision reflects a reclassification of our Neuromodulation business from our MedSurg segment to our newly created Rhythm and Neuro segment. We have revised prior year amounts to conform to the current year's presentation (as denoted with an asterisk (*) throughout). There was no revision to operating segments or reporting units as a result of the organizational change.

A reconciliation of the totals reported for the reportable segments to the applicable line items in our accompanying consolidated statements of operations is as follows (in millions, except percentages):

	Year Ended December 31,		
Net sales	**2018**	**2017**	**2016**
MedSurg*	$ 3,007	$ 2,742	$ 2,445
Rhythm and Neuro*	3,041	2,808	2,649
Cardiovascular	3,777	3,500	3,292
	$ 9,823	**$ 9,048**	**$ 8,386**

	Year Ended December 31,		
Depreciation expense	**2018**	**2017**	**2016**
MedSurg*	$ 72	$ 68	$ 60
Rhythm and Neuro*	91	91	91
Cardiovascular	133	120	118
	$ 296	**$ 279**	**$ 270**

	Year Ended December 31,		
Income (loss) before income taxes	**2018**	**2017**	**2016**
MedSurg*	$ 1,102	$ 984	$ 852
Rhythm and Neuro*	655	537	402
Cardiovascular	1,117	988	946
Operating income allocated to reportable segments	2,875	2,509	2,200
Corporate expenses, including hedging activities	(372)	(252)	(179)
Intangible asset impairment charges, acquisition-related, restructuring- and restructuring-related and litigation-related net (charges) credits	(398)	(407)	(1,029)
Amortization expense	(599)	(565)	(545)
Operating income (loss)	1,506	1,285	447
Other expense, net	(85)	(353)	(270)
	$ 1,422	**$ 933**	**$ 177**

	Year Ended December 31,		
Operating income as a percentage of segment net sales	**2018**	**2017**	**2016**
MedSurg*	36.7%	35.9%	34.9%
Rhythm and Neuro*	21.5%	19.1%	15.2%

Cardiovascular	29.6%	28.2%	28.7%

	As of December 31,	
Total assets	**2018**	**2017**
MedSurg*	$ 1,846	$ 1,871
Rhythm and Neuro*	1,696	1,607
Cardiovascular	1,954	1,824
Total assets allocated to reportable segments	5,497	5,302
Goodwill	7,911	6,998
Other intangible assets, net	6,372	5,837
All other corporate assets	1,219	905
	$ 20,999	**$ 19,042**

Long-lived assets	As of December 31, 2018	2017	2016
U.S.	$ 1,061	$ 1,065	$ 1,082
Ireland	242	210	181
Other countries	478	422	367
Property, plant and equipment, net	1,782	1,697	1,630
Goodwill	7,911	6,998	6,678
Other intangible assets, net	6,372	5,837	5,883
	$ 16,064	**$ 14,531**	**$ 14,191**

NOTE O – REVENUE

We generate revenue primarily from the sale of single-use medical devices and present revenue net of sales taxes in our consolidated statements of operations. The following tables disaggregate our revenue from contracts with customers by business and geographic region (in millions):

	Year Ended December 31,		
Businesses	**2018**	**2017**	**2016**
Endoscopy			
U.S.	$ 980	$ 894	$ 770
International	781	724	670
Worldwide	1,762	1,619	1,440
Urology and Pelvic Health			
U.S.	864	785	711
International	381	339	294
Worldwide	1,245	1,124	1,005
Cardiac Rhythm Management			
U.S.	1,159	1,135	1,110
International	792	760	740
Worldwide	1,951	1,895	1,850
Electrophysiology			
U.S.	150	136	129
International	161	142	114
Worldwide	311	278	243
Neuromodulation			
U.S.	624	517	474
International	155	118	82
Worldwide	779	635	556
Interventional Cardiology			
U.S.	1,154	1,122	1,013
International	1,436	1,297	1,268
Worldwide	2,590	2,419	2,281
Peripheral Interventions			
U.S.	608	575	552

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

International	579	506	459
Worldwide	1,187	1,081	1,011
Total Company			
U.S.	5,538	5,162	4,759
International	4,286	3,885	3,627
Net Sales	**$ 9,823**	**$ 9,048**	**$ 8,386**

Geographic Regions	Year Ended December 31, 2018	2017	2016
U.S.	$ 5,538	$ 5,162	$ 4,759
EMEA (Europe, Middle East and Africa)	2,176	1,940	1,802
APAC (Asia-Pacific)	1,727	1,587	1,492
LACA (Latin America and Canada)	383	358	333
	$ 9,823	**$ 9,048**	**$ 8,386**
Emerging Markets (1)	**$ 1,072**	**$ 909**	**$ 793**

(1) Emerging Markets is defined as certain countries that we believe have strong growth potential based on their economic conditions, healthcare sectors and our global capabilities. Currently, we include 20 countries in our definition of Emerging Markets.

Contract liabilities are classified within *Other current liabilities* and *Other long-term liabilities* on our accompanying consolidated balance sheets. Our deferred revenue balance was $373 million as of December 31, 2018 and $411 million as of January 1, 2018. Our contractual liabilities are primarily composed of deferred revenue related to the LATITUDE Patient Management System. Revenue is recognized over the average service period which is based on device and patient longevity. We recognized revenue of $117 million in 2018 that was included in the above January 1, 2018 contract liability balance. We have elected not to disclose the transaction price allocated to unsatisfied performance obligations when the original expected contract duration is one year or less. In addition, we have not identified material unfulfilled performance obligations for which revenue is not currently deferred. Refer to *Note A – Significant Accounting Policies* for additional information on our accounting policies relating to revenue recognition.

NOTE P – CHANGES IN OTHER COMPREHENSIVE INCOME

The following table provides the reclassifications out of *Other comprehensive income, net of tax*:

(in millions)	Foreign Currency Translation Adjustments	Net Change in Derivative Financial Instruments	Net Change in Available-for-Sale Securities	Net Change in Defined Benefit Pensions and Other Items	Total
Balance as of December 31, 2017	**$ (32)**	**$ 1**	**$ (1)**	**$ (27)**	**$ (59)**
Other comprehensive income (loss) before reclassifications	—	96	—	(2)	94
(Income) loss amounts reclassified from accumulated other comprehensive income	(21)	14	1	4	(3)
Total other comprehensive income (loss)	(21)	110	—	2	91
Balance as of December 31, 2018	**$ (53)**	**$ 111**	**$ —**	**$ (25)**	**$ 33**

(in millions)	Foreign Currency Translation Adjustments	Net Change in Derivative Financial Instruments	Net Change in Available-for-Sale Securities	Net Change in Defined Benefit Pensions and Other Items	Total

Balance as of December 31, 2016	**$ (79)**	**$ 107**	**$ (6)**	**$ (21)**	**$ 1**
Other comprehensive income (loss) before reclassifications	48	(65)	(10)	(8)	(35)
(Income) loss amounts reclassified from accumulated other comprehensive income	—	(42)	15	2	(25)
Total other comprehensive income (loss)	48	(106)	5	(6)	(59)
Balance as of December 31, 2017	**$ (32)**	**$ 1**	**$ (1)**	**$ (27)**	**$ (59)**

Refer to *Note D – Hedging Activities and Fair Value Measurements* for further detail on the reclassifications related to derivatives.

We adopted Update No. 2016-01 in the first quarter of 2018, and as a result of adopting the standard, we recorded a cumulative effect adjustment to retained earnings for unrealized gains and losses for available-for-sale securities previously recorded to *Accumulated other comprehensive income (loss), net of tax*.

The gains and losses on defined benefit and pension items before reclassifications and gains and losses on defined benefit and pension items reclassified from *Accumulated other comprehensive income (loss), net of tax* were reduced by immaterial income tax impacts in 2018 and in 2017.

NOTE Q – NEW ACCOUNTING PRONOUNCEMENTS

Periodically, new accounting pronouncements are issued by the FASB or other standard setting bodies. Recently issued standards typically do not require adoption until a future effective date. Prior to their effective date, we evaluate the pronouncements to determine the potential effects of adoption on our consolidated financial statements.

Standards to be Implemented

ASC Update No. 2016-02

In February 2016, the FASB issued ASC Update No. 2016-02, *Leases* (Topic 842). The purpose of Update No. 2016-02 is to increase the transparency and comparability among organizations by recognizing lease assets and liabilities on the balance sheet, including those previously classified as operating leases under current U.S. GAAP, and disclosing key information about leasing arrangements. Topic 842, as amended, is effective for public entities for annual periods beginning after December 15, 2018, including interim periods within those annual periods.

We currently plan to adopt the standard using the transition method provided by ASC Update No. 2018-11, *Leases (Topic 842): Targeted Improvements*. Under this method, we will initially apply the new leasing rules on January 1, 2019, rather than at the earliest comparative period presented in the financial statements. Prior periods presented will be in accordance with the existing lease guidance.

Upon transition, we plan to apply the package of practical expedients permitted under Topic 842 transition guidance to our entire lease portfolio at January 1, 2019. As a result, we are not required to reassess (i) whether any expired or existing contracts are or contain leases, (ii) the classification of any expired or existing leases, and (iii) initial direct costs for any existing leases. Furthermore, we will be electing not to separate lease and non-lease components for the majority of our leases. Instead, for these applicable classes of underlying assets, we will account for each separate lease component and the non-lease components associated with that lease component, as a single lease component.

As a result of adopting Topic 842, we expect to recognize additional right-of-use assets and corresponding liabilities for our existing lease portfolio on our consolidated balance sheets of approximately $300 million, with no material impact to our consolidated statements of operations or consolidated statements of cash flows. For the first quarter of 2019, we will provide additional disclosures in the notes to our consolidated statements of operations regarding our leasing portfolio, including key judgements and assumptions and the discount rate used in calculating our right-of-use assets and corresponding liabilities. Please refer to *Note F - Leases and Other Purchase Obligations* for information regarding our lease portfolio as of December 31, 2018 as accounted for under ASC Topic 840, *Leases*.

To ensure we meet the reporting and disclosure requirements of Topic 842, we implemented in 2018 a new lease administration and lease accounting system that will track all our material leasing arrangements. In addition, in the first quarter of 2019, we designed new internal controls to ensure the completeness and accuracy of the transition adjustment and financial reporting under Topic 842. We also established monitoring controls to ensure we have appropriate mechanisms in place to identify material leases timely, particularly contracts that may contain embedded lease features.

ASC Update No. 2016-13

In June 2016, the FASB issued ASC Update No. 2016-13, *Financial Instruments – Credit Losses* (Topic 326)*: Measurement of Credit Losses on Financial Instruments*. The purpose of Update No. 2016-13 is to replace the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. Update No. 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods

within those annual periods. Early adoption is permitted for annual periods beginning after December 15, 2018. We are in the process of determining the effect that the adoption will have on our financial position and results of operations.

ASC Update No. 2018-15

In August 2018, the FASB issued ASC Update No. 2018-15, *Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.* The purpose of Update No. 2018-15 is to align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). Update No. 2018-15 is effective for annual periods beginning after December 15, 2019, including interim periods within those annual periods. Early adoption is permitted, including adoption in any interim period. We are in the process of determining the effect that the adoption will have on our financial position and results of operations.

No other new accounting pronouncements, issued or effective, during the period had, or is expected to have, a material impact on our consolidated financial statements.

NOTE R - EMPLOYEE RETIREMENT PLANS

Following our 2006 acquisition of Guidant, we sponsored the Guidant Supplemental Retirement Plan, a frozen, non-qualified defined benefit plan for certain former officers and employees of Guidant. The Guidant Supplemental Retirement Plan was partially funded through a Rabbi Trust that contains segregated company assets within restricted cash used to pay the benefit obligations related to the plan.

We also maintain an Executive Retirement Plan, a defined benefit plan covering executive officers and division presidents. Participants may retire with unreduced benefits once retirement conditions have been satisfied. In addition, we maintain retirement plans covering certain international employees.

We use a December 31 measurement date for these plans and record the underfunded portion as a liability within non-current liabilities, with the current portion within accrued expenses, on the consolidated balance sheets, recognizing changes in the funded status through *OCI*. The outstanding obligation is as follows:

	As of December 31, 2018			
(in millions)	Accumulated Benefit Obligation (ABO)	Projected Benefit Obligation (PBO)	Fair value of Plan Assets	Underfunded PBO Recognized
Executive Retirement Plan	$ 17	$ 20	$ —	$ 20
Guidant Supplemental Retirement Plan (frozen)	30	30	—	30
International Retirement Plans	166	182	107	75
	213	**$ 232**	**$ 107**	**$ 125**

	As of December 31, 2017			
(in millions)	Accumulated Benefit Obligation (ABO)	Projected Benefit Obligation (PBO)	Fair value of Plan Assets	Underfunded PBO Recognized
Executive Retirement Plan	$ 18	$ 21	$ —	$ 21
Guidant Supplemental Retirement Plan (frozen)	33	33	—	33
International Retirement Plans	138	153	87	66

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

$ 189	$ 207	$ 87	$ 120

A rollforward of the changes in the PBO for our funded retirement plans is as follows:

	Year Ended December 31,	
(in millions)	**2018**	**2017**
Beginning obligations	**$ 207**	**$ 152**
Acquired and established plans (1)	23	33
Service costs	14	13
Interest costs	4	4
Actuarial (gain) loss	(1)	2
Plan amendments and assumption changes	(2)	(1)
Benefits paid	(10)	(8)
Impact of foreign currency fluctuations	(3)	11
Ending obligation	**$ 232**	**$ 207**

(1) Plans obtained through acquisition and other increases in connection with our international operations.

The critical assumptions associated with our employee retirement plans as of December 31, 2018 and are as follows:

	Discount Rate	Expected Return on Plan Assets	Rate of Compensation Increase
Executive Retirement Plan	4.00%	N/A	3.00%
Guidant Supplemental Retirement Plan (frozen)	4.25%	N/A	N/A
International Retirement Plans	0.50% - 2.34%	1.90% - 4.10%	1.50% - 6.78%

The critical assumptions associated with our employee retirement plans as of December 31, 2017 are as follows:

	Discount Rate	Expected Return on Plan Assets	Rate of Compensation Increase
Executive Retirement Plan	3.25%	N/A	3.00%
Guidant Supplemental Retirement Plan (frozen)	3.50%	N/A	N/A
International Retirement Plans	0.50% - 2.25%	2.50% - 4.10%	1.50% - 6.78%

We base our discount rate on the rates of return available on high-quality bonds with maturities approximating the expected period over which benefits will be paid. The rate of compensation increase is based on historical and expected rate increases. We base our rate of expected return on plan assets on historical experience, our investment guidelines and expectations for long-term rates of return. Our international pension plan assets are invested in a variety of securities, primarily equity securities and government bonds. These securities are considered Level 1 and Level 2 investments.

A rollforward of the changes in the fair value of plan assets for our funded retirement plans is as follows:

	Year Ended December 31,	
(in millions)	**2018**	**2017**

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Beginning fair value	**$ 87**	**$ 54**
Acquired and established plans (1)	16	19
Actual return on plan assets	(2)	6
Employer contributions	14	10
Participant contributions	2	1
Benefits paid	(10)	(8)
Impact of foreign currency fluctuations	—	4
Ending fair value	**$ 107**	**$ 87**

(1) Plans obtained through acquisition and other increases in connection with our international operations.

We also sponsor a voluntary 401(k) Retirement Savings Plan for eligible employees. We match 200 percent of employee elective deferrals for the first two percent of employee eligible compensation and 50 percent of employee elective deferrals greater than

two percent, but not exceeding six percent, of employee eligible compensation. Total expense for our matching contributions to the plan was $87 million in 2018, $79 million in 2017 and $72 million in 2016.

QUARTERLY RESULTS OF OPERATIONS
(in millions, except per share data)
(unaudited)

	Three Months Ended			
	Mar 31,	June 30,	Sept 30,	Dec 31,
2018				
Net sales	$ 2,379	$ 2,490	$ 2,393	$ 2,561
Gross profit	1,707	1,751	1,720	1,832
Operating income (loss)	407	392	388	319
Net income (loss)	298	555	432	386
Net income (loss) per common share - basic	$ 0.22	$ 0.40	$ 0.31	$ 0.28
Net income (loss) per common share - assuming dilution	$ 0.21	$ 0.40	$ 0.31	$ 0.27
2017				
Net sales	$ 2,160	$ 2,257	$ 2,222	$ 2,408
Gross profit	1,510	1,625	1,585	1,735
Operating income (loss)	364	225	377	319
Net income (loss)	290	146	283	(615)
Net income (loss) per common share - basic	$ 0.21	$ 0.11	$ 0.21	$ (0.45)
Net income (loss) per common share - assuming dilution	$ 0.21	$ 0.11	$ 0.20	$ (0.45)

Our reported results for 2018 included amortization expense, intangible asset impairment charges, acquisition-related net charges, restructuring and restructuring-related net charges, litigation-related net charges, certain investment impairment charges and certain discrete tax items (after tax) of: $157 million in the first quarter, $13 million in the second quarter, $53 million in the third quarter and $166 million in the fourth quarter. These after-tax net charges consisted primarily of: $328 million credit related to certain discrete tax items and $520 million of amortization expense.

Our reported results for 2017 included amortization expense, intangible asset impairment charges, acquisition-related net charges, restructuring and restructuring-related net charges, litigation-related net charges, investment impairment charges and certain discrete tax items (after tax) of: $107 million in the first quarter, $298 million in the second quarter, $149 million in the third quarter and $1.095 billion in the fourth quarter. These after-tax net charges consisted primarily of: $861 million related to the estimated one-time net income tax charge related to the enactment of the TCJA in December 2017, $492 million of amortization expense and $172 million of litigation-related net charges.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (CEO) and Executive Vice President and Chief Financial Officer (CFO), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018 pursuant to Rule 13a-15(b) of the Securities Exchange Act of 1934, as amended. Disclosure controls and procedures are designed to ensure that material information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and ensure that such material information is accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. Based on their evaluation, our CEO and CFO concluded that as of December 31, 2018, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Management's annual report on our internal control over financial reporting is contained in Item 7 of this Annual Report.

Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting

The report of Ernst & Young LLP on our internal control over financial reporting is contained in Item 7 of this Annual Report.

Changes in Internal Control over Financial Reporting

During the quarter ended December 31, 2018, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is set forth in our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2018 and is incorporated into this Annual Report by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is set forth in our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2018 and is incorporated into this Annual Report by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is set forth in our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2018 and is incorporated into this Annual Report by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this Item is set forth in our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2018 and is incorporated into this Annual Report by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is set forth in our Proxy Statement for the 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2018 and is incorporated into this Annual Report by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements.

The response to this portion of Item 15 is set forth under Item 8.

(a)(2) Financial Statement Schedules.

The response to this portion of Item 15 (Schedule II) follows the signature page to this report. All other financial statement schedules are not required under the related instructions or are inapplicable and therefore have been omitted.

(a)(3) Exhibits (* documents filed or furnished with this report, ** certain schedules and exhibits omitted pursuant to Item 601(b)(2) of Regulation S-K. We agree to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request, # compensatory plans or arrangements)

EXHIBIT NO.	TITLE
2.1	Purchase Agreement among American Medical Systems Holdings, Inc., Endo Health Solutions Inc. and the Company, dated as of March 2, 2015 (incorporated by reference to Exhibit 2.1, Quarterly Report on Form 10-Q for the quarter ended March 30, 2015, File No. 1-11083).**
3.1	Restated By-laws of the Company (incorporated herein by reference to Exhibit 3.1, Current Report on Form 8-K dated September 19, 2011, File No. 1-11083)
3.2	Third Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.2, Annual Report on Form 10-K for the year ended December 31, 2007, File No. 1-11083).
4.1	Specimen Certificate for shares of the Company's Common Stock (incorporated herein by reference to Exhibit 4.1, Registration No. 33-46980).
4.2	Description of Capital Stock contained in Exhibits 3.1 and 3.2.
4.3	Indenture dated as of June 25, 2004, between the Company and JPMorgan Chase Bank, as Trustee (incorporated herein by reference to Exhibit 4.1, Current Report on Form 8-K dated June 25, 2004, File No. 1-11083).
4.4	Indenture dated as of November 18, 2004, between the Company and J.P. Morgan Trust Company, National Association, as Trustee (incorporated herein by reference to Exhibit 4.1, Current Report on Form 8-K dated November 18, 2004, File No. 1-11083).

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

4.5	First Supplemental Indenture dated as of April 21, 2006 (incorporated herein by reference to Exhibit 99.4, Current Report on Form 8-K dated April 21, 2006, File No. 1-11083).
4.6	Second Supplemental Indenture dated as of April 21, 2006 (incorporated herein by reference to Exhibit 99.6, Current Report on Form 8-K dated April 21, 2006, File No. 1-11083).
4.7	Form of Global Security for the 5.125% Notes due 2017 in the aggregate principal amount of $250,000,000 (incorporated herein by reference to Exhibit 4.3, Current Report on Form 8-K dated November 18, 2004, File No. 1-11083).

4.8	Form of Global Security for the 6.25% Notes due 2035 in the aggregate principal amount of $350,000,000, and form of Notice to holders thereof (incorporated herein by reference to Exhibit 4.2, Current Report on Form 8-K dated November 17, 2005 and Exhibit 99.7, Current Report on Form 8-K dated April 21, 2006, File No. 1-11083).
4.9	Indenture dated as of June 1, 2006, between the Company and JPMorgan Chase Bank, N.A., as Trustee (incorporated herein by reference to Exhibit 4.1, Current Report on Form 8-K dated June 9, 2006, File No. 1-11083).
4.10	6.000% Senior Note due January 15, 2020 in the aggregate principal amount of $850,000,000 (incorporated herein by reference to Exhibit 4.3, Current Report on Form 8-K dated December 10, 2009, File No. 1-11083).
4.11	7.375% Senior Note due January 15, 2040 in the aggregate principal amount of $300,000,000 (incorporated herein by reference to Exhibit 4.4, Current Report on Form 8-K dated December 10, 2009, File No. 1-11083).
4.12	2.650% Senior Note due October 1, 2018 in the aggregate principal amount of $500,000,000 (incorporated herein by reference to Exhibit 4.2, Current Report on Form 8-K dated August 8, 2013, File No. 1-11083).
4.13	4.125% Senior Note Due October 1, 2023 in the aggregate principle amount of $450,000,000 (incorporated herein by reference to Exhibit 4.3, Current Report on Form 8-K dated August 8, 2013, File No. 1-11083).
4.14	2.850% Senior Notes due 2020 (incorporated herein by reference to Exhibit 4.2, Current Report on Form 8-K dated May 12, 2015, File No. 1-11083).
4.15	3.375% Senior Notes due 2022 (incorporated herein by reference to Exhibit 4.3, Current Report on Form 8-K dated May 12, 2015, File No. 1-11083).
4.16	3.850% Senior Notes due 2025 (incorporated herein by reference to Exhibit 4.4, Current Report on Form 8-K dated May 12, 2015, File No. 1-11083).
4.17	Indenture dated as of May 29, 2013, between the Company and U.S. Bank Association, as Trustee (incorporated herein by reference to Exhibit 4.1, Registration Statement on Form S-3 (File No 333-188918) filed on May 29, 2013).
4.18	4.000% Senior Notes Due 2028 (incorporated herein by reference to Exhibit 4.2, Current Report on Form 8-K dated February 26, 2018, File No. 1-11083).
10.1	Form of Omnibus Amendment dated as of December 21, 2006, among the Company, Boston Scientific Funding Corporation, Variable Funding Capital Company LLC, Victory Receivables Corporation and The Bank of Tokyo-Mitsubishi UFJ, Ltd., New York Branch (Amendment No. 1 to Receivables Sale Agreement and Amendment No. 9 to Credit and Security Agreement) (incorporated herein by reference to Exhibit 10.2, Annual Report on 10-K for the year ended December 31, 2006, File No. 1-11083).
10.2	Form of Amended and Restated Receivables Sale Agreement dated as of November 7, 2007 between the Company and each of its Direct or Indirect Wholly-Owned Subsidiaries that Hereafter Becomes a Seller Hereunder, as the Sellers, and Boston Scientific Funding LLC, as the Buyer (incorporated herein by

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

reference to Exhibit 10.2, Current Report on Form 8-K dated November 7, 2007, File No. 1-11083).

10.3	Credit Agreement dated as of April 18, 2012, by and among the Company, the several lenders parties thereto, and Bank of America, N.A., as Syndication Agent, and JPMorgan Chase Bank, N.A., as Administrative Agent (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated April 18, 2012, File No. 1-11083).

10.4	Credit Agreement dated as of April 10, 2015, by and among Boston Scientific Corporation, the several lenders parties thereto, Bank of America, N.A., as Syndication Agent and JPMorgan Chase Bank, N.A., as Administrative Agent (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated April 14, 2015, File No. 1-11083).
10.5	First Amendment, dated as of October 23, 2015, to the Credit Agreement, dated as of April 10, 2015, among Boston Scientific Corporation, the several lenders party thereto, Bank of America, N.A., as Syndication Agent, and JPMorgan Chase Bank, N.A., as Administrative Agent (incorporated by reference to Exhibit 10.5, Annual Report on Form 10-K for the year ended December 31, 2015, File No. 1-11083).*
10.6	License Agreement among Angiotech Pharmaceuticals, Inc., Cook Incorporated and the Company dated July 9, 1997, and related Agreement dated December 13, 1999 (incorporated herein by reference to Exhibit 10.6, Annual Report on Form 10-K for the year ended December 31, 2002, File No. 1-11083).
10.7	Amendment between Angiotech Pharmaceuticals, Inc. and the Company dated November 23, 2004 modifying July 9, 1997 License Agreement among Angiotech Pharmaceuticals, Inc., Cook Incorporated and the Company (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated November 23, 2004, File No. 1-11083).
10.8	Transaction Agreement, dated as of January 8, 2006, as amended, between the Company and Abbott Laboratories (incorporated herein by reference to Exhibit 10.47, Exhibit 10.48, Exhibit 10.49 and Exhibit 10.50, Annual Report on Form 10-K for year ended December 31, 2005 and Exhibit 10.1, Current Report on Form 8-K dated April 7, 2006, File No. 1-11083).
10.9	Settlement Agreement among Johnson & Johnson, Guidant LLC and the Company, dated as of February 13, 2015 (incorporated by reference to Exhibit 10.1, Quarterly Report on Form 10-Q for the quarter ended March 30, 2015, File No. 1-11083).
10.10	Form of Non-Qualified Stock Option Agreement (Non-Employee Directors) (incorporated herein by reference to Exhibit 10.5, Current Report on Form 8-K dated December 10, 2004, File No. 1-11083).#
10.11	Form of Restricted Stock Award Agreement (Non-Employee Directors) (incorporated herein by reference to Exhibit 10.6, Current Report on Form 8-K dated December 10, 2004, File No. 1-11083).#
10.12	Form of Restricted Stock Award Agreement (Non-Employee Directors) under the 2011 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.1, Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, File No. 1-11083).#
10.13	Form of Boston Scientific Corporation Excess Benefit Plan, as amended (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated June 29, 2005 and Exhibit 10.4, Current Report on Form 8-K dated December 16, 2008, File No. 1-11083).#
10.14	Form of Trust under the Boston Scientific Corporation Excess Benefit Plan (incorporated herein by reference to Exhibit 10.2, Current Report on Form 8-K dated June 29, 2005, File No. 1-11083).#

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

10.15	Boston Scientific Corporation Deferred Bonus Plan (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated May 11, 2010, File No. 1-11083).#
10.16	Boston Scientific Corporation 401(k) Retirement Savings Plan, Amended and Restated, effective as of January 1, 2011 (incorporated herein by reference to Exhibit 10.39, Annual Report on Form 10-K for year ended December 31, 2010, File No. 1-11083).#
10.17	Amendment to Boston Scientific Corporation 401(k) Retirement Savings Plan, Amended and Restated, effective as of January 1, 2011 (incorporated herein by reference to Exhibit 10.44, Annual Report on Form 10-K for the year ended December 31, 2011, File No. 1-11083).#

10.18	Form of Second Amendment of Boston Scientific Corporation 401(k) Retirement Savings Plan, Amended and Restated (incorporated herein by reference to Exhibit 10.2, Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, File No. 1-11083).#
10.19	Form of Third Amendment of the Boston Scientific Corporation 401(k) Retirement Savings Plan, Amended and Restated (incorporated herein by reference to Exhibit 10.1, Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, File No. 1-11083).#
10.20	Boston Scientific Corporation 2000 Long-Term Incentive Plan, as amended (incorporated herein by reference to Exhibit 10.20, Annual Report on Form 10-K for the year ended December 31, 1999, Exhibit 10.18, Annual Report on Form 10-K for the year ended December 31, 2001, Exhibit 10.1, Current Report on Form 8-K dated December 22, 2004, Exhibit 10.3, Current Report on Form 8-K dated May 9, 2005, and Exhibit 10.3, Current Report on Form 8-K dated December 16, 2008, File No. 1-11083).#
10.21	Boston Scientific Corporation 2003 Long-Term Incentive Plan, as Amended and Restated, Effective June 1, 2008 (incorporated herein by reference to Exhibit 10.1, Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, File No. 1-11083).#
10.22	Boston Scientific Corporation 2011 Long-Term Incentive Plan, as amended (incorporated herein by reference to Exhibit 10.49, Annual Report on Form 10-K for the year ended December 31, 2011, File No. 1-11083).#
10.23	Form of Non-Qualified Stock Option Agreement (vesting over three years) (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated December 10, 2004, File No. 1-11083).#
10.24	Form of Non-Qualified Stock Option Agreement (vesting over four years) (incorporated herein by reference to Exhibit 10.2, Current Report on Form 8-K dated December 10, 2004, File No. 1-11083).#
10.25	Form of Non-Qualified Stock Option Agreement (vesting over two years) (incorporated herein by reference to Exhibit 10.20, Annual Report on Form 10-K for the year ended December 31, 2007, File No. 1-11083).#
10.26	Form of Non-Qualified Stock Option Agreement dated July 1, 2005 (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated July 1, 2005, File No. 1-11083).#
10.27	Form of Stock Option Agreement (with one year service requirement for vesting upon Retirement) (incorporated herein by reference to Exhibit 10.6, Quarterly Report on Form 10-Q dated September 30, 2010, File No. 1-11083).#
10.28	Form of Restricted Stock Award Agreement (Non-Employee Directors) under the 2003 and 2011 Long-Term Incentive Plans (incorporated herein by reference to Exhibit 10.4, Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, File No. 1-11083).#
10.29	Form of Non-Qualified Stock Option Agreement under the 2011 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.5, Quarterly

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Report on Form 10-Q for the quarter ended June 30, 2011, File No. 1-11083).#

10.30 Form of Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Total Shareholder Return) (incorporated herein by reference to Exhibit 10.70, Annual Report on Form 10-K for the year ended December 31, 2011, File No. 1-11083).#

10.31 Form of Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Free Cash Flow) (incorporated herein by reference to Exhibit 10.71, Annual Report on Form 10-K for the year ended December 31, 2011, File No. 1-11083).#

10.32	Form of Deferred Stock Unit Award Agreement under the 2011 Long-Term Incentive Plan (Special) (incorporated herein by reference to Exhibit 10.72, Annual Report on Form 10-K for the year ended December 31, 2011, File No. 1-11083).#
10.33	Form of Change in Control Agreement between the Company and certain Executive Officers (incorporated herein by reference to Exhibit 10.3, Current Report on Form 8-K dated December 15, 2009, File No. 1-11083).#
10.34	Form of Offer Letter between the Company and Timothy A. Pratt dated April 9, 2008 (incorporated herein by reference to Exhibit 10.1, Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, File No. 1-11083).#
10.35	Form of Offer Letter dated September 6, 2011 between the Company and Michael F. Mahoney, as supplemented September 13, 2011 (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated September 19, 2011, File No. 1-11083).#
10.36	Form of Amendment, dated February 14, 2012, to Offer Letter dated September 6, 2011 between the Company and Michael F. Mahoney, as supplemented September 13, 2011 (incorporated herein by reference to Exhibit 10.100, Annual Report on Form 10-K for the year ended December 31, 2011, File No. 1-11083).#
10.37	Form of Offer Letter by and between the Company and Joseph M. Fitzgerald dated February 27, 2014 (incorporated by reference to Exhibit 10.2, Quarterly Report on Form 10-Q for the quarter ended March 30, 2015, File No. 1-11083). #
10.38	Form of Offer Letter by and between the Company and Kevin J. Ballinger dated December 14, 2012 (incorporated by reference to Exhibit 10.3, Quarterly Report on Form 10-Q for the quarter ended March 30, 2015, File No. 1-11083).#
10.39	The Boston Scientific Deferred Compensation Option Program (incorporated herein by reference to Exhibit 4.1, Registration No. 333-98755).#
10.40	Boston Scientific Corporation Domestic Relocation Policy Tier 5 Executive Officer Homeowner, effective January 2007 (incorporated herein by reference to Exhibit 10.118, Annual Report on Form 10-K for the year ended December 31, 2012, File No. 1-11083).#
10.41	Form of Letter to Key Management Personnel re: Change in Control Agreement (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated February 28, 2013, File No. 1-11083).
10.42	Form of Offer Letter by and between the Company and Daniel J. Brennan, dated October 22, 2013 (incorporated herein by reference to Exhibit 10.2, Current Report on Form 8-K dated October 24, 2013 File No. 1-11083). #
10.43	Boston Scientific Corporation Total Shareholder Return Performance Share Program, Performance Period January 1, 2014 - December 31, 2016 (incorporated herein by reference to Exhibit 10.2, Current Report on Form 8-K dated October 22, 2013 File No. 1-11083).#
10.44	Boston Scientific Corporation Free Cash Flow Performance Share Program, Performance Period January 1, 2014 - December 31, 2014 (incorporated herein

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

by reference to Exhibit 10.3, Current Report on Form 8-K dated October 22, 2013 File No. 1-11083).#

10.45	Form of 2011 Long-Term Incentive Plan Global Deferred Stock Unit Award Agreement (incorporated herein by reference to Exhibit 10.3, Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 File No. 1-11083).#

10.46	Form of 2011 Long-Term Incentive Plan Global Non-Qualified Stock Option Agreement (incorporated herein by reference to Exhibit 10.4, Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 File No. 1-11083).#
10.47	Boston Scientific Corporation U.S. Severance Plan for Exempt Employees, as amended and restated, effective August 1, 2013 (incorporated herein by reference to Exhibit 10.6, Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 File No. 1-11083).#
10.48	Boston Scientific Corporation Non-Employee Director Deferred Compensation Plan, as amended and restated, effective January 1, 2009 (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated October 28, 2008, File No. 1-11083).#
10.49	Boston Scientific Corporation Non-Employee Director Deferred Compensation Plan, as amended and restated, effective January 1, 2014 (incorporated herein by reference to Exhibit 10.6, Quarterly Report on Form 10-Q for the quarter ended September 30, 2013 File No. 1-11083).#
10.50	Form of Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (2014 Total Shareholder Return) incorporated herein by reference to Exhibit 10.99, Annual Report on Form 10-K for the year ended December 31, 2013 File No. 1-11083).#
10.51	Form of Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (2014 Free Cash Flow) incorporated herein by reference to Exhibit 10.100, Annual Report on Form 10-K for the year ended December 31, 2013 File No. 1-11083).#
10.52	Boston Scientific Corporation 2006 Global Employee Stock Ownership Plan, as amended and restated, effective July 1, 2014 (incorporated herein by reference to Exhibit 10.1, Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, File No. 1-11083). #
10.53	Boston Scientific Corporation 2015 Annual Bonus Plan, effective as of January 1, 2015 (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated October 28, 2014, File No. 1-11083). #
10.54	Boston Scientific Corporation 2015 Total Shareholder Return Performance Share Program (incorporated herein by reference to Exhibit 10.2, Current Report on Form 8-K dated October 28, 2014, File No. 1-11083). #
10.55	Boston Scientific Corporation 2015 Free Cash Flow Performance Share Program (incorporated herein by reference to Exhibit 10.3, Current Report on Form 8-K dated October 28, 2014, File No. 1-11083). #
10.56	Boston Scientific Corporation Executive Retirement Plan, as amended and restated effective August 1, 2016 (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated July 25, 2016, File No. 1-11083). #
10.57	Form of Non-Qualified Stock Option Agreement under the 2011 Long-Term Incentive Plan (Non-Employee Directors) (incorporated herein by reference to Exhibit 10.1, Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, File No. 1-11083). #

10.58	Form of Restricted Stock Award Agreement under the 2011 Long-Term Incentive Plan (Non-Employee Directors) (incorporated herein by reference to Exhibit 10.2, Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, File No. 1-11083). #
10.59	Form of Deferred Stock Unit Award Agreement under the 2011 Long-Term Incentive Plan (Non-Employee Directors) (incorporated herein by reference to Exhibit 10.3, Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, File No. 1-11083). #

10.60	Form of Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Total Shareholder Return) (incorporated herein by reference to Exhibit 10.4, Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, File No. 1-11083). #
10.61	Form of Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Free Cash Flow) (incorporated herein by reference to Exhibit 10.5, Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, File No. 1-11083). #
10.62	First Amendment to Boston Scientific Corporation Deferred Bonus Plan, effective January 1, 2015 (incorporated herein by reference to Exhibit 10.6, Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, File No. 1-11083). #
10.63	Boston Scientific Corporation 2016 Annual Bonus Plan, effective as of January 1, 2016 (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K filed October 5, 2015, File No. 001-11083).#
10.64	Boston Scientific Corporation 2016 Total Shareholder Return Performance Share Program (incorporated herein by reference to Exhibit 10.2, Current Report on Form 8-K filed October 5, 2015, File No. 001-11083)#
10.65	Boston Scientific Corporation 2016 Free Cash Flow Performance Share Program (incorporated herein by reference to Exhibit 10.3, Current Report on Form 8-K filed October 5, 2015, File No. 001-11083)#
10.66	Form of Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Total Shareholder Return) (incorporated by reference to Exhibit 10.4, Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, File No. 1-11083). #
10.67	Form of Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Free Cash Flow) (incorporated by reference to Exhibit 10.5, Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, File No. 1-11083). #
10.68	Form of Offer Letter by and between the Company and Edward Mackey dated December 24, 2014 (incorporated herein by reference to Exhibit 10.1, Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, File No. 1-11083). #
10.69	Form of Global Non-Qualified Stock Option Agreement under the 2011 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.2, Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, File No. 1-11083). #
10.70	Form of Global Deferred Stock Unit Award Agreement under the 2011 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.3, Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, File No. 1-11083). #
10.71	Form of 2016 Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Total Shareholder Return) (incorporated herein by reference to Exhibit 10.4, Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, File No. 1-11083). #

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

10.72	Form of 2016 Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Free Cash Flow) (incorporated herein by reference to Exhibit 10.5, Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, File No. 1-11083). #
10.73	Boston Scientific Corporation 2017 Annual Bonus Plan, effective as of January 1, 2017 (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K filed November 22, 2016, File No. 001-11083). #
10.74	Boston Scientific Corporation 2017 Total Shareholder Return Performance Share Program (incorporated herein by reference to Exhibit 10.2, Current Report on Form 8-K filed November 22, 2016, File No. 001-11083). #

10.75	Boston Scientific Corporation 2017 Free Cash Flow Performance Share Program (incorporated herein by reference to Exhibit 10.3, Current Report on Form 8-K filed November 22, 2016, File No. 001-11083). #
10.76	Credit Agreement dated as of August 4, 2017 by and among Boston Scientific Corporation, the several lenders party thereto, Bank of America, N.A. and Wells Fargo Bank, National Association, as Syndication Agents and JPMorgan Chase Bank, N.A., as Administrative Agent (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K filed on August 7, 2017, File No. 1-11083).
10.77	Boston Scientific Corporation 2018 Annual Bonus Plan, effective as of January 1, 2018 (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K filed November 17, 2017, File No. 001-11083).
10.78	Boston Scientific Corporation 2018 Total Shareholder Return Performance Share Program (incorporated herein by reference to Exhibit 10.2, Current Report on Form 8-K filed November 17, 2017 File No. 1-11083).
10.79	Boston Scientific Corporation 2018 Free Cash Flow Performance Share Program (incorporated herein by reference to Exhibit 10.3, Current Report on Form 8-K filed November 17, 2017, File No. 001-11083). #
10.80	Form of Global Non-Qualified Stock Option Agreement under the 2011 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.1, Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, File No. 1-11083).#
10.81	Form of Global Deferred Stock Unit Award Agreement under the 2011 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.2, Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, File No. 1-11083).#
10.82	Form of 2017 Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Total Shareholder Return) (incorporated herein by reference to Exhibit 10.3, Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, File No. 1-11083).#
10.83	Form of 2017 Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Free Cash Flow) (incorporated herein by reference to Exhibit 10.4, Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, File No. 1-11083).#
10.84	Second Amended and Restated Credit and Security Agreement, dated as of February 7, 2017, by and among Boston Scientific Funding LLC, Boston Scientific Corporation, Wells Fargo Bank, National Association and Sumitomo Mitsui Banking Corporation, New York Branch, as Lenders, Wells Fargo Bank, National Association and SMBC Nikko Securities America, Inc., as Co-Agents, and Wells Fargo Bank, National Association, as Administrative Agent (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated February 10, 2017, File No. 1-11083).
10.85	Second Amended and Restated Receivables Sale Agreement, dated as of February 7, 2017, by and among Boston Scientific Corporation, each of its direct or indirect wholly-owned subsidiaries that become a seller thereunder and Boston Scientific Funding LLC (incorporated herein by reference to Exhibit 10.2,

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Current Report on Form 8-K dated February 10, 2017, File No. 1-11083).

10.86	Form of Global Non-Qualified Stock Option Agreement under the 2011 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.1, Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, File No. 1-11083).#
10.87	Form of Global Deferred Stock Unit Award Agreement under the 2011 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.2, Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, File No. 1-11083).#

10.88	Form of 2018 Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Total Shareholder Return) (incorporated herein by reference to Exhibit 10.3, Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, File No. 1-11083).#
10.89	Form of 2018 Performance Share Unit Award Agreement under the 2011 Long-Term Incentive Plan (Free Cash Flow) (incorporated herein by reference to Exhibit 10.4, Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, File No. 1-11083).#
10.90	Form of Acquisition-Related Non-Qualified Stock Option Award Agreement under the 2011 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.5, Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, File No. 1-11083). #
10.91	Form of Acquisition-Related Deferred Stock Unit Award Agreement under the 2011 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.6, Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, File No. 1-11083). #
10.92	Form of Restricted Stock Award Agreement for Non-Employee Directors under the 2011 Long-Term Incentive Plan incorporated herein by reference to Exhibit 10.7, Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, File No. 1-11083). #
10.93	Form of Deferred Stock Unit Award Agreement for Non-Employee Directors under the 2011 Long-Term Incentive Plan incorporated herein by reference to Exhibit 10.8, Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, File No. 1-11083). #
10.94	Form of Non-Qualified Stock Option Award Agreement for Non-Employee Directors under the 2011 Long-Term Incentive Plan# (incorporated herein by reference to Exhibit 10.9, Current Report on Form 10-Q quarter ended March 31, 2018, File No. 1-11083). #
10.95	Boston Scientific Corporation 2019 Annual Bonus Plan, effective as of January 1, 2019 (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K filed November 19, 2018, File No. 001-11083).#
10.96	Boston Scientific Corporation 2019 Total Shareholder Return Performance Share Program (incorporated herein by reference to Exhibit 10.2, Current Report on Form 8-K filed November 19, 2018 File No. 1-11083).#
10.97	Boston Scientific Corporation 2019 Free Cash Flow Performance Share Program (incorporated herein by reference to Exhibit 10.3, Current Report on Form 8-K filed November 19, 2018, File No. 1-11083).#
10.98	Credit Agreement dated as of August 20, 2018, by and among Boston Scientific Corporation, the several lenders parties thereto, Bank of America, N.A., MUFG Bank, LTD., and Sumitomo Mitsui Banking Corporation, as Syndication Agents, and Wells Fargo Bank, N.A., as Administrative Agent (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K filed August 21, 2018, File No. 1-11083.)
10.99	BTG plc Acquisition Rule 2.7 Announcement, dated November 20, 2018. (incorporated herein by reference to Exhibit 2.1, Current Report on Form 8-K filed November 23, 2018, File No. 1-11083).

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

10.100	BTG plc Cooperation Agreement, dated November 20, 2018. (incorporated herein by reference to Exhibit 2.2, Current Report on Form 8-K filed November 23, 2018, File No. 1-11083).
10.101	BTG plc Shareholder Undertaking of Invesco Asset Management Limited, dated November 20, 2018 (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K filed November 23, 2018, File No. 1-11083).
10.102	BTG plc Shareholder Undertaking of Novo Holdings A/S, dated November 20, 2018 (incorporated herein by reference to Exhibit 10.2, Current Report on Form 8-K filed November 23, 2018, File No. 1-11083).

10.103	BTG plc Shareholder Undertaking of Woodford Asset Management Limited, dated November 20, 2018 (incorporated herein by reference to Exhibit 10.3, Current Report on Form 8-K filed November 23, 2018, File No. 1-11083).
10.104	BTG plc Form of Director Undertaking (incorporated herein by reference to Exhibit 10.4, Current Report on Form 8-K filed November 23, 2018, File No. 1-11083).
10.105	Bridge Credit Agreement, dated as of November 20, 2018 by and among Boston Scientific Corporation, the lenders party thereto and Barclays Bank PLC, as administrative agent, bookrunner and lead arranger (incorporated herein by reference to Exhibit 10.5, Current Report on Form 8-K filed November 23, 2018, File No. 1-11083).
10.106	Credit Agreement, dated as of December 19, 2018, by and among Boston Scientific Corporation, the lenders party thereto and Wells Fargo Bank, National Association, as administrative agent and Bank of America, N.A. as syndication agent (incorporated herein by reference to Exhibit 10.1, Current Report on Form 8-K dated December 21, 2018, File No. 1-11083).
10.107	First Amendment to Credit Agreement, dated as of December 19, 2018, among Boston Scientific Corporation, the lenders party thereto and Wells Fargo Bank, National Association as administrative agent (incorporated herein by reference to Exhibit 10.2, Current Report on Form 8-K dated December 21, 2018, File No. 1-11083).
10.108	Term Loan Credit Agreement, dated as of December 19, 2018, among Boston Scientific Corporation, the lenders party thereto and Barclays Bank PLC, as administrative agent, Bank of America, N.A., Wells Fargo Bank, National Association and JPMorgan Chase Bank, N.A., as syndication agents (incorporated herein by reference to Exhibit 10.3, Current Report on Form 8-K dated December 21, 2018, File No. 1-11083).
21*	List of the Boston Scientific's subsidiaries as of January 31, 2019.
23*	Consent of Independent Registered Public Accounting Firm, Ernst & Young LLP.
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

101*	Interactive Data Files Pursuant to Rule 405 of Regulation S-T: (i) the Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016; (ii) the Consolidated Statements of Comprehensive Income (Loss) as of December 31, 2018, 2017 and 2016; (iii) the Consolidated Balance Sheets as of December 31, 2018 and 2017; (iv) the Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018, 2017 and 2016; (v) the Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016; (vi) the notes to the Consolidated Financial Statements; and (vii) Schedule II - Valuation and Qualifying Accounts

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 19, 2019

Boston Scientific Corporation

By: /s/ Daniel J. Brennan

Daniel J. Brennan
Executive Vice President and Chief Financial Officer
(duly authorized officer and principal financial and accounting officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Dated: February 19, 2019

By: /s/ Daniel J. Brennan

Daniel J. Brennan
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Dated: February 19, 2019

By: /s/ Nelda J. Connors

Nelda J. Connors
Director

Dated: February 19, 2019 By: /s/ Charles J. Dockendorff

Charles J. Dockendorff
Director

Dated: February 19, 2019 By: /s/ Yoshiaki Fujimori

Yoshiaki Fujimori
Director

Dated: February 19, 2019 By: /s/ Donna A. James

Donna A. James
Director

Dated: February 19, 2019 By: /s/ Edward J. Ludwig

Edward J. Ludwig
Director

Dated: February 19, 2019 By: /s/ Stephen P. MacMillan

Stephen P. MacMillan
Director

Dated: February 19, 2019

By: /s/ Michael F. Mahoney

Michael F. Mahoney
Director, Chairman of the Board,
President and Chief Executive Officer
(Principal Executive Officer)

Dated: February 19, 2019 By: /s/ David J. Roux

David J. Roux
Director

Dated: February 19, 2019 By: /s/ John E. Sununu

John E. Sununu
Director

Dated: February 19, 2019 By: /s/ Ellen M. Zane

Ellen M. Zane
Director

Schedule II
VALUATION AND QUALIFYING ACCOUNTS
(in millions)

Description	Balance at Beginning of Year	Charges to Costs and Expenses (a)	Deductions to Allowances for Uncollectible Accounts (b)	Charges to (Deductions from) Other Accounts (c)	Balance at End of Year
Year Ended December 31, 2018:					
Allowances for uncollectible accounts (d)	$ 98	19	(19)	(30)	$ 68
Year Ended December 31, 2017:					
Allowances for uncollectible accounts and sales returns and allowances	$ 119	14	(18)	(17)	$ 98
Year Ended December 31, 2016:					
Allowances for uncollectible accounts and sales returns and allowances	$ 119	9	(11)	2	$ 119

(a) Represents allowances for uncollectible accounts established through selling, general and administrative expenses.
(b) Represents actual write-offs of uncollectible accounts.
(c) Represents net change in allowances for sales returns, recorded as contra-revenue.
(d) Due to the adoption of FASB ASC Topic 606 effective January 1, 2018, the allowance for sales returns has been prospectively reclassified from *Trade accounts receivable, net* to *Other current liabilities* within the consolidated balance sheets and is not included in the ending balance for 2018 above. Prior period balances remain unchanged.

EXHIBIT P

10-Q 1 mdt-2019q3x10q.htm 10-Q

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

x **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended January 25, 2019

Commission File Number 001-36820

MEDTRONIC PUBLIC LIMITED COMPANY
(Exact name of registrant as specified in its charter)

Ireland	**98-1183488**
(State of incorporation)	(I.R.S. Employer Identification No.)

20 On Hatch, Lower Hatch Street
Dublin 2, Ireland
(Address of principal executive offices) (Zip Code)
+353 1 438-1700
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes x No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes x No ☐

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer x	Accelerated filer ☐	Emerging growth company ☐
Non-accelerated filer ☐	Smaller Reporting Company ☐	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 1(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ☐ No x

As of February 27, 2019, 1,341,150,970 ordinary shares, par value $0.0001, and 1,872 A preferred shares, par value $1.00, of the registrant were outstanding.

TABLE OF CONTENTS

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Medtronic plc
Consolidated Statements of Income
(Unaudited)

	Three months ended		Nine months ended	
(in millions, except per share data)	**January 25, 2019**	**January 26, 2018**	**January 25, 2019**	**January 26, 2018**
Net sales	$ 7,546	$ 7,369	$ 22,411	$ 21,809
Costs and expenses:				
Cost of products sold	2,265	2,194	6,672	6,669
Research and development expense	561	559	1,736	1,664
Selling, general, and administrative expense	2,596	2,523	7,798	7,642
Amortization of intangible assets	436	461	1,327	1,375
Restructuring charges, net	26	7	112	23
Certain litigation charges	63	61	166	61
Gain on sale of businesses	—	—	—	(697)
Other operating expense, net	57	128	278	360
Operating profit	1,542	1,436	4,322	4,712
Other non-operating (income) expense, net	(71)	139	(309)	(67)
Interest expense	243	270	726	829
Income before income taxes	1,370	1,027	3,905	3,950
Income tax provision	99	2,419	437	2,320
Net income (loss)	1,271	(1,392)	3,468	1,630
Net (income) loss attributable to noncontrolling interests	(2)	3	(9)	14
Net income (loss) attributable to Medtronic	$ 1,269	$ (1,389)	$ 3,459	$ 1,644
Basic earnings (loss) per share	$ 0.95	$ (1.03)	$ 2.57	$ 1.21
Diluted earnings (loss) per share	$ 0.94	$ (1.03)	$ 2.54	$ 1.20
Basic weighted average shares outstanding	1,342.8	1,354.0	1,348.1	1,357.2
Diluted weighted average shares outstanding	1,352.7	1,354.0	1,359.5	1,368.9

The accompanying notes are an integral part of these consolidated financial statements.

Medtronic plc
Consolidated Statements of Comprehensive Income
(Unaudited)

(in millions)	Three months ended		Nine months ended	
	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Net income (loss)	$ 1,271	$ (1,392)	$ 3,468	$ 1,630
Other comprehensive income (loss), net of tax:				
Unrealized gain (loss) on available-for-sale securities	32	(14)	23	41
Currency translation	128	897	(1,127)	1,525
Net change in retirement obligations	17	(3)	65	11
Unrealized (loss) gain on derivatives	(23)	(202)	317	(346)
Other comprehensive income (loss)	154	678	(722)	1,231
Comprehensive income (loss) including noncontrolling interests	1,425	(714)	2,746	2,861
Comprehensive (income) loss attributable to noncontrolling interests	(2)	3	(6)	14
Comprehensive income (loss) attributable to Medtronic	$ 1,423	$ (711)	$ 2,740	$ 2,875

The accompanying notes are an integral part of these consolidated financial statements.

Medtronic plc
Consolidated Balance Sheets
(Unaudited)

(in millions)	January 25, 2019	April 27, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,703	$ 3,669
Investments	5,439	7,558
Accounts receivable, less allowances of $197 and $193, respectively	5,854	5,987
Inventories, net	3,866	3,579
Other current assets	2,015	2,187
Total current assets	20,877	22,980
Property, plant, and equipment	10,746	10,259
Accumulated depreciation	(6,153)	(5,655)
Property, plant, and equipment, net	4,593	4,604
Goodwill	40,003	39,543
Other intangible assets, net	20,835	21,723
Tax assets	1,496	1,465
Other assets	926	1,078
Total assets	$ 88,730	$ 91,393
LIABILITIES AND EQUITY		
Current liabilities:		
Current debt obligations	$ 1,356	$ 2,058
Accounts payable	1,706	1,628
Accrued compensation	1,796	1,988
Accrued income taxes	648	979
Other accrued expenses	3,347	3,431
Total current liabilities	8,853	10,084
Long-term debt	23,674	23,699
Accrued compensation and retirement benefits	1,313	1,425
Accrued income taxes	2,874	3,051
Deferred tax liabilities	1,356	1,423

Other liabilities	719	889
Total liabilities	38,789	40,571
Commitments and contingencies (Note 17)		
Shareholders' equity:		
Ordinary shares— par value $0.0001, 2.6 billion shares authorized, 1,340,592,569 and 1,354,218,154 shares issued and outstanding, respectively	—	—
Additional paid-in capital	26,518	28,127
Retained earnings	25,769	24,379
Accumulated other comprehensive loss	(2,458)	(1,786)
Total shareholders' equity	49,829	50,720
Noncontrolling interests	112	102
Total equity	49,941	50,822
Total liabilities and equity	$ 88,730	$ 91,393

The accompanying notes are an integral part of these consolidated financial statements.

Medtronic plc
Consolidated Statements of Cash Flows
(Unaudited)

(in millions)	Nine months ended January 25, 2019	Nine months ended January 26, 2018
Operating Activities:		
Net income	$ 3,468	$ 1,630
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,992	1,980
Provision for doubtful accounts	55	36
Deferred income taxes	(205)	(1,042)
Stock-based compensation	228	270
Gain on sale of businesses	—	(697)
Investment loss	—	227
Other, net	111	12
Change in operating assets and liabilities, net of acquisitions and divestitures:		
Accounts receivable, net	(140)	19
Inventories, net	(367)	(318)
Accounts payable and accrued liabilities	211	13
Other operating assets and liabilities	(433)	1,516
Net cash provided by operating activities	4,920	3,646
Investing Activities:		
Acquisitions, net of cash acquired	(1,615)	(111)
Proceeds from sale of businesses	—	6,058
Additions to property, plant, and equipment	(799)	(776)
Purchases of investments	(1,987)	(2,479)
Sales and maturities of investments	4,159	3,060
Other investing activities	(3)	(5)
Net cash (used in) provided by investing activities	(245)	5,747
Financing Activities:		
Change in current debt obligations, net	(696)	(391)
Issuance of long-term debt	3	21
Payments on long-term debt	(29)	(4,167)
Dividends to shareholders	(2,022)	(1,870)
Issuance of ordinary shares	891	333

Repurchase of ordinary shares	(2,728)	(1,964)
Other financing activities	10	(88)
Net cash used in financing activities	(4,571)	(8,126)
Effect of exchange rate changes on cash and cash equivalents	(70)	124
Net change in cash and cash equivalents	34	1,391
Cash and cash equivalents at beginning of period	3,669	4,967
Cash and cash equivalents at end of period	$ 3,703	$ 6,358
Supplemental Cash Flow Information		
Cash paid for:		
Income taxes	$ 1,206	$ 911
Interest	540	651

The accompanying notes are an integral part of these consolidated financial statements.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

1. Basis of Presentation

The accompanying unaudited consolidated financial statements of Medtronic plc and its subsidiaries (Medtronic plc, Medtronic, or the Company) have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S.) (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, the consolidated financial statements include all of the adjustments necessary for a fair statement in conformity with U.S. GAAP. Certain reclassifications have been made to prior year financial statements to conform to classifications used in the current year. For the purpose of providing more concise consolidated statements of income, amounts previously reported in *acquisition-related items* were reclassified to *selling, general, and administrative expense* and *other operating expense, net;* amounts previously reported in *divestiture-related items* were reclassified to *selling, general, and administrative expense;* amounts previously reported in *special charge* were reclassified to *other operating expense, net*, and amounts previously reported in *investment loss* and *interest income* were reclassified to *other non-operating (income) expense, net*.

Operating results for interim periods are not necessarily indicative of results that may be expected for the fiscal year as a whole. The preparation of the financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and the related disclosures at the date of the financial statements and during the reporting period. Actual results could materially differ from these estimates.

The accompanying unaudited consolidated financial statements include the accounts of Medtronic plc, its wholly-owned subsidiaries, entities for which the Company has a controlling financial interest, and variable interest entities for which the Company is the primary beneficiary. Intercompany transactions and balances have been fully eliminated in consolidation.

The accompanying unaudited consolidated financial statements and related notes should be read in conjunction with the audited consolidated financial statements of the Company and related notes included in the Company's Annual Report on Form 10-K for the fiscal year ended April 27, 2018. The Company's fiscal years 2019, 2018, and 2017 will end or ended on April 26, 2019, April 27, 2018, and April 28, 2017, respectively.

2. New Accounting Pronouncements

Recently Adopted

In May 2014, the Financial Accounting Standards Board (FASB) issued amended revenue recognition guidance to clarify the principles for recognizing revenue from contracts with customers. The guidance requires an entity to recognize revenue in an amount that reflects the consideration to which an entity expects to be entitled in exchange for the transfer of goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. The Company adopted this guidance using the modified retrospective method in the first quarter of fiscal year 2019, and elected to apply the guidance only to contracts that were not completed as of the date of initial application. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In January 2016, the FASB issued guidance which requires equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income. The guidance also includes a simplified impairment assessment of equity investments without readily determinable fair values and presentation and disclosure changes. The Company adopted this guidance in the first quarter of fiscal year 2019 on

a prospective basis. As a result of the adoption, the Company reclassified $47 million from *accumulated other comprehensive loss* to the opening balance of *retained earnings* as of April 28, 2018.

In March 2017, the FASB issued guidance which changes the financial statement presentation requirements for pension and other postretirement benefit expense. While service cost will continue to be recognized in the same financial statement line items as other current employee compensation costs, the guidance requires all other non-service components of net benefit costs to be classified and presented outside of income from operations. The Company adopted this guidance in the first quarter of fiscal year 2019, and the consolidated statements of income were retrospectively adjusted. For the three and nine months ended January 26, 2018, the Company reclassified $10 million of expense and $4 million of income, respectively, of non-service components of net periodic benefit costs, which were previously presented as a component of operating profit, to *other non-operating (income) expense, net*.

In August 2018, the SEC adopted a final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, that amends certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. The amendments also expanded the disclosure requirements on the analysis of shareholders' equity for interim financial statements, in which registrants

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

must now analyze changes in shareholders' equity, in the form of reconciliation, for the current and comparative year-to-date periods, with subtotals for each interim period. This final rule was effective on November 5, 2018. The Company has adopted all relevant disclosure requirements, with the exception of the shareholders' equity interim disclosures, which is allowed to be adopted in a future interim period.

Not Yet Adopted

In February 2016, the FASB issued guidance which requires lessees to recognize right-of-use assets and lease liabilities on the balance sheet. The guidance will be adopted using the modified retrospective method by applying the new guidance as of the transition date with a cumulative-effect adjustment to the opening balance of retained earnings. The guidance is effective for the Company beginning in the first quarter of fiscal year 2020. The Company is evaluating the impact of the lease guidance on the Company's consolidated financial statements and anticipates recording additional assets and corresponding liabilities on its consolidated balance sheets related to operating leases within its lease portfolio upon adoption of the guidance.

3. Revenue

The Company's revenues are principally derived from device-based medical therapies and services related to cardiac rhythm disorders, cardiovascular disease, renal disease, neurological disorders and diseases, spinal conditions and musculoskeletal trauma, chronic pain, urological and digestive disorders, ear, nose, and throat conditions, and diabetes conditions as well as advanced and general surgical care products, respiratory and monitoring solutions, and neurological surgery technologies. The Company's primary customers include hospitals, clinics, third-party health care providers, distributors, and other institutions, including governmental health care programs and group purchasing organizations.

The table below illustrates net sales by segment and division for the three and nine months ended January 25, 2019 and January 26, 2018:

	Three months ended		Nine months ended	
(in millions)	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Cardiac Rhythm & Heart Failure	$ 1,397	$ 1,457	$ 4,295	$ 4,314
Coronary & Structural Heart	913	886	2,736	2,557
Aortic, Peripheral & Venous	476	457	1,424	1,348
Cardiac and Vascular Group	2,786	2,800	8,455	8,219
Surgical Innovations	1,434	1,384	4,224	4,024
Respiratory, Gastrointestinal, & Renal	690	657	1,999	2,455
Minimally Invasive Therapies Group	2,124	2,041	6,223	6,479
Spine	655	661	1,963	1,969
Brain Therapies	650	585	1,867	1,682
Specialty Therapies	407	398	1,196	1,132
Pain Therapies	314	300	942	833
Restorative Therapies Group	2,026	1,944	5,968	5,616
Diabetes Group	610	584	1,765	1,495

Total	$ 7,546	$ 7,369	$ 22,411	$ 21,809

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

The table below illustrates net sales by market geography for each segment for the three and nine months ended January 25, 2019 and January 26, 2018:

	U.S.[1]		Non-U.S. Developed Markets[2]		Emerging Markets[3]	
	Three months ended		Three months ended		Three months ended	
(in millions)	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Cardiac and Vascular Group	$ 1,369	$ 1,395	$ 924	$ 934	$ 493	$ 471
Minimally Invasive Therapies Group	930	862	796	807	398	372
Restorative Therapies Group	1,354	1,300	435	429	237	215
Diabetes Group	348	355	213	185	49	44
Total	$ 4,001	$ 3,912	$ 2,368	$ 2,355	$ 1,177	$ 1,102

	U.S.[1]		Non-U.S. Developed Markets[2]		Emerging Markets[3]	
	Nine months ended		Nine months ended		Nine months ended	
(in millions)	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Cardiac and Vascular Group	$ 4,240	$ 4,151	$ 2,766	$ 2,716	$ 1,449	$ 1,352
Minimally Invasive Therapies Group	2,659	2,902	2,396	2,455	1,168	1,122
Restorative Therapies Group	4,005	3,779	1,275	1,217	688	620
Diabetes Group	1,006	856	619	521	140	118
Total	$ 11,910	$ 11,688	$ 7,056	$ 6,909	$ 3,445	$ 3,212

(1) U.S. includes the United States and U.S. territories.
(2) Non-U.S. developed markets include Japan, Australia, New Zealand, Korea, Canada, and the countries of Western Europe.
(3) Emerging markets include the countries of the Middle East, Africa, Latin America, Eastern Europe, and the countries of Asia that are not included in the non-U.S. developed markets, as defined above.

The Company sells its products through direct sales representatives and independent distributors. Additionally, a portion of the Company's revenue is generated from consignment inventory maintained at hospitals. The Company recognizes revenue when control is transferred to the customer. For products sold through direct sales representatives and independent distributors, control is transferred upon shipment or upon delivery, based on the contract terms and legal requirements. For consignment inventory, control is transferred when the product is used or implanted. Payment terms vary depending on the country of sale, type of customer, and type of product.

If a contract contains more than one performance obligation, the transaction price is allocated to each performance obligation based on relative standalone selling price. Shipping and handling is treated as a fulfillment activity rather than a promised service, and therefore, is not considered a performance obligation. Taxes assessed by a governmental authority that are both imposed on, and concurrent with, a specific revenue producing transaction and collected by the Company from customers (for example, sales, use, value added, and some excise taxes) are not included in revenue. For contracts that have an original duration of one year or less, the Company uses the practical expedient applicable to such contracts and does not adjust the transaction price for the time value of money.

The amount of revenue recognized reflects sales rebates and returns, which are estimated based on sales terms, historical experience, and trend analysis. In estimating rebates, the Company considers the lag time between the point of sale and the payment of the rebate claim, the stated rebate rates, and other relevant information. The Company records adjustments to rebates and returns reserves as increases or decreases of revenue. At January 25, 2019, $715 million of rebates were classified as *other accrued expenses* and $426 million of rebates were classified as a reduction of *accounts receivable* in the consolidated balance sheets. At April 27, 2018, $614 million of rebates were classified as *other accrued expenses* and $376 million of rebates were classified as a reduction of *accounts receivable* in the consolidated balance sheets. The Company includes obligations for returns in *other accrued expenses* in the consolidated balance sheets and the right-of-return asset in o*ther current assets* in the consolidated balance sheets. The right-of-return asset at January 25, 2019 and right-of-return liability at January 25, 2019 and April 27, 2018 were not material. There was no right-of-return asset at April 27, 2018 as the liability was recorded net of the asset under previous guidance. For the three and nine months ended January 25, 2019, adjustments to rebate and return reserves recognized in revenue that were included in the rebate and return reserves at the beginning of the period were not material.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

The Company offers warranties on various products. For standard, assurance-type warranties, the Company estimates the costs that may be incurred under its warranties and records a liability in the amount of such costs at the time the product is sold. The amount of the reserve is equal to the net costs to repair or otherwise satisfy the obligation. The Company includes the warranty obligation in *other accrued expenses* and *other liabilities* in the consolidated balance sheets. For extended, service-type warranties, a portion of the transaction price is allocated to the performance obligation. Warranty obligations at January 25, 2019 and April 27, 2018 were not material.

Deferred Revenue and Remaining Performance Obligations

The Company records a deferred revenue liability if a customer pays consideration before the Company transfers a good or service to the customer. Deferred revenue primarily represents remote monitoring services and equipment maintenance, for which consideration is received at the same time as consideration for the device or equipment. Deferred revenue also includes extended, service-type warranties. Revenue related to remote monitoring services, equipment maintenance, and service-type warranties is recognized over the service period as time elapses.

Deferred revenue at January 25, 2019 and April 27, 2018 was $308 million and $289 million, respectively. At January 25, 2019 and April 27, 2018, $209 million and $196 million was included in *other accrued expenses*, respectively, and $99 million and $93 million was included in *other liabilities*, respectively. During the nine months ended January 25, 2019, the Company recognized $170 million of revenue that was included in deferred revenue as of April 27, 2018.

Remaining performance obligations include deferred revenue and amounts the Company expects to receive for goods and services that have not yet been delivered or provided under existing, noncancellable contracts with minimum purchase commitments, primarily related to consumables for previously sold equipment as well as remote monitoring services and equipment maintenance. For contracts that have an original duration of one year or less, the Company has elected the practical expedient applicable to such contracts and does not disclose the transaction price for remaining performance obligations at the end of each reporting period and when the Company expects to recognize this revenue. At January 25, 2019, the estimated revenue expected to be recognized in future periods related to performance obligations that are unsatisfied for executed contracts with an original duration of one year or more was approximately $700 million. The Company expects to recognize revenue on the majority of these remaining performance obligations over the next three years.

4. Acquisitions

The Company had acquisitions during the three and nine months ended January 25, 2019 that were accounted for as business combinations. The assets and liabilities of the businesses acquired were recorded and consolidated on the acquisition date at their respective fair values. Goodwill resulting from business combinations is largely attributable to future yet to be defined technologies, new customer relationships, existing workforce of the acquired businesses, and synergies expected to arise after the Company's acquisition of these businesses. The pro forma impact of these acquisitions was not significant, either individually or in the aggregate, to the results of the Company for the three or nine months ended January 25, 2019 and January 26, 2018. The results of operations of acquired businesses have been included in the Company's consolidated statements of income since the date each business was acquired.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

The acquisition date fair values of the assets acquired and liabilities assumed were as follows:

(in millions)	Mazor Robotics	All Other	Total
Cash and cash equivalents	$ 109	$ 3	$ 112
Investments	52	—	52
Accounts receivable	10	2	12
Inventory	8	27	35
Other current assets	2	3	5
Property, plant, and equipment	3	29	32
Goodwill	1,214	146	1,360
Other intangible assets	400	211	611
Tax assets	—	6	6
Total assets acquired	1,798	427	2,225
Current liabilities	56	45	101
Accrued income taxes	3	5	8
Deferred tax liabilities	65	—	65
Total liabilities assumed	124	50	174
Net assets acquired	$ 1,674	$ 377	$ 2,051

Mazor Robotics

On December 18, 2018, the Company's Restorative Therapies Group acquired Mazor Robotics (Mazor), a pioneer in the field of robotic guidance systems. The acquisition of Mazor strengthens the Company's position as a global leader in enabling technologies for spine surgery. The Company offers a fully-integrated procedural solution for surgical planning, execution and confirmation by combining the Company's spine implants, navigation, and intra-operative imaging technology with Mazor's robotic-assisted surgery systems. Total consideration for the transaction, net of cash acquired, was $1.6 billion, consisting of $1.3 billion of cash and $246 million of a previously-held equity investment in Mazor. Based upon a preliminary acquisition valuation, the Company acquired $384 million of technology-based intangible assets and $16 million of tradenames with estimated useful lives of 10 years and $1.2 billion of goodwill. The goodwill is primarily attributable to pull-through revenue, future yet to be defined technologies, and assembled workforce. The goodwill is not deductible for tax purposes.

During the three and nine months ended January 25, 2019, the Company recognized $51 million of costs incurred in connection with the acquisition of Mazor, including payouts for unvested stock options and investment banker and other transaction fees, which were recognized in *selling, general, and administrative expense* in the consolidated statements of income. Revenue and net income (loss) attributable to Mazor since the date of acquisition included in the consolidated statements of income were not material for the three or nine months ended January 25, 2019.

Refer to Note 2 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended April 27, 2018 for additional information on the Company's fiscal year 2018 acquisitions.

Acquired In-Process Research & Development

In-process research and development (IPR&D) acquired outside of a business combination is expensed immediately. During the nine months ended January 25, 2019, the Company acquired $15 million of IPR&D in connection with an asset acquisition, which was recognized in *other operating expense, net* in the consolidated statements of income. The Company did not acquire any IPR&D in connection with an asset acquisition during the three months ended January 25, 2019 or the three and nine months ended January 26, 2018.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Contingent Consideration

Certain of the Company's business combinations involve potential payment of future consideration that is contingent upon the achievement of certain product development milestones and/or contingent on the acquired business reaching certain performance milestones. A liability is recorded for the estimated fair value of the contingent consideration on the acquisition date. The fair value of the contingent consideration is remeasured at each reporting period, and the change in fair value is recognized within *other operating expense, net* in the consolidated statements of income. Contingent consideration payments made soon after the acquisition date are classified as investing activities in the consolidated statements of cash flows. Contingent consideration payments not made soon after the acquisition date that are related to the acquisition date fair value are reported as financing activities in the consolidated statements of cash flows, and amounts paid in excess of the original acquisition date fair value are reported as operating activities in the consolidated statements of cash flows.

The fair value of contingent consideration at January 25, 2019 and April 27, 2018 was $148 million and $173 million, respectively. At January 25, 2019, $99 million was recorded in *other accrued expenses* and $49 million was recorded in *other liabilities* in the consolidated balance sheets. At April 27, 2018, $108 million was recorded in *other accrued expenses* and $65 million was recorded in *other liabilities* in the consolidated balance sheets.

The following table provides a reconciliation of the beginning and ending balances of contingent consideration:

	Three months ended		Nine months ended	
(in millions)	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Beginning balance	$ 203	$ 190	$ 173	$ 246
Purchase price contingent consideration	5	13	51	28
Payments	(1)	(20)	(8)	(66)
Change in fair value	(59)	(12)	(68)	(37)
Ending balance	$ 148	$ 171	$ 148	$ 171

The fair value of contingent consideration is measured using projected payment dates, discount rates, probabilities of payment, and projected revenues (for revenue-based consideration). Projected revenues are based on the Company's most recent internal operational budgets and long-range strategic plans. Changes in projected payment dates, discount rates, probabilities of payment, and projected revenues may result in adjustments to the fair value measurement. The recurring Level 3 fair value measurements of contingent consideration for which a liability is recorded include the following significant unobservable inputs:

(in millions)	Fair Value at January 25, 2019	Valuation Technique	Unobservable Input	Range
Revenue and other performance-based payments	$97	Discounted cash flow	Discount rate	11.5% - 32.5%
			Probability of payment	100%

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

			Projected fiscal year of payment	2019 - 2025
			Discount rate	5.5%
Product development and other milestone-based payments	$51	Discounted cash flow	Probability of payment	75% - 100%
			Projected fiscal year of payment	2019 - 2027

5. Divestitures

On July 29, 2017, the Company completed the sale of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses within the Minimally Invasive Therapies Group segment to Cardinal Health, Inc. (Cardinal). As a result of the transaction, the Company received proceeds of $6.1 billion, which was recorded in *proceeds from sale of businesses* in the consolidated statements of cash flows, and recognized a before-tax gain of $697 million, which was recognized within *gain on sale of businesses* in the consolidated statements of income. Among the product lines included in the divestiture were dental and animal health, chart paper, wound care, incontinence, electrodes, SharpSafety, thermometry, perinatal protection, blood collection, compression, and enteral feeding offerings. The divestiture also included 17 dedicated manufacturing sites.

During the nine months ended January 26, 2018, the Company recognized expenses incurred in connection with the divestiture of $115 million, primarily comprised of professional services, including banker, legal, tax, and advisory fees, as well as $16 million of accelerated stock compensation expense related to the acceleration of the vesting period for employees that transferred

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

with the divestiture. Expenses incurred in connection with the divestiture were recognized in *selling, general, and administrative expense* in the consolidated statements of income. There were no divestiture-related expenses during the three months ended January 26, 2018 or the three and nine months ended January 25, 2019.

The divestiture of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses did not meet the criteria to be classified as discontinued operations, as such, the results of operations of these businesses are included within net income through the date of the divestiture.

6. Restructuring

For the three and nine months ended January 25, 2019, the Company recognized $66 million and $256 million in restructuring charges, net of $3 million and $8 million of accrual adjustments, respectively.

For the three and nine months ended January 26, 2018, the Company recognized $30 million and $62 million in restructuring charges, net of $2 million and $15 million of accrual adjustments, respectively. For the three and nine months ended January 26, 2018, the Company recognized $32 million of charges related to the Enterprise Excellence restructuring program, and for the three and nine months ended January 26, 2018, the Company recognized no charges and $45 million of charges, respectively, related to the Cost Synergies restructuring program.

Accrual adjustments relate to certain employees identified for termination finding other positions within the Company, cancellations of employee terminations, and employee termination benefits being less than initially estimated.

Enterprise Excellence

In the third quarter of fiscal year 2018, the Company announced its Enterprise Excellence restructuring program, which is expected to leverage the Company's global size and scale, as well as enhance the customer and employee experience, with a focus on three objectives: global operations, functional optimization, and commercial optimization. Primary activities of the restructuring program include integrating and enhancing global manufacturing and supply processes, systems and site presence, enhancing and leveraging global operating models across several enabling functions, and optimizing certain commercial processes, systems, and models.

The Company estimates that, in connection with its Enterprise Excellence restructuring program, it will recognize pre-tax exit and disposal costs and other costs associated with the restructuring program across all segments of approximately $1.6 billion to $1.8 billion, the majority of which are expected to be incurred by the end of fiscal year 2022. Approximately half of the estimated charges are related to employee termination benefits. The remaining restructuring charges are costs associated with the restructuring program, such as salaries for employees supporting the program and consulting expenses. These charges are recognized within *restructuring charges, net, cost of products sold,* and *selling, general, and administrative expense* in the consolidated statements of income.

For the three and nine months ended January 25, 2019, the Company recognized $69 million and $264 million in charges, respectively. Restructuring charges included $21 million and $58 million, respectively, recognized within *cost of products sold* and $19 million and $73 million, respectively, recognized within *selling, general, and administrative expense* in the consolidated statements of income.

For the three and nine months ended January 26, 2018, the Company recognized $32 million in charges. Restructuring charges included $13 million recognized within *cost of products sold* and $10 million recognized within *selling, general, and administrative expense* in the consolidated statements of income.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

The following table summarizes the activity related to the Enterprise Excellence restructuring program for the nine months ended January 25, 2019:

(in millions)	Employee Termination Benefits	Associated Costs[1]	Asset Write-Downs[2]	Other Costs	Total
April 27, 2018	$ 27	$ 2	$ —	$ —	$ 29
Charges	107	131	13	13	264
Cash payments	(97)	(128)	—	(5)	(230)
Settled non-cash	—	—	(13)	—	(13)
January 25, 2019	$ 37	$ 5	$ —	$ 8	$ 50

(1) Associated costs include costs incurred as a direct result of the restructuring program, such as salaries for employees supporting the program and consulting expenses.
(2) Recognized within *selling, general, and administrative expense* in the consolidated statements of income.

Cost Synergies

The cost synergies program related to administrative office optimization, manufacturing and supply chain infrastructure, and certain general and administrative savings was achieved as part of the Covidien plc (Covidien) integration and completed in the third quarter of fiscal year 2018. Restructuring charges incurred throughout the life of the initiative affecting all segments were primarily related to employee termination costs and costs related to manufacturing and facility closures.

A summary of the restructuring accrual and related activity is presented below:

(in millions)	Employee Termination Benefits	Other Costs	Total
April 27, 2018	$ 116	$ 22	$ 138
Cash payments	(34)	(18)	(52)
Accrual adjustments	(8)	—	(8)
January 25, 2019	$ 74	$ 4	$ 78

For the three and nine months ended January 25, 2019, the Company recognized accrual adjustments of $1 million and $8 million, respectively.

For the three months ended January 26, 2018, the Company recognized no charges, and for the nine months ended January 26, 2018, the Company recognized $45 million in charges. During the three and nine months ended January 26, 2018, the Company recognized accrual adjustments of $2 million and $15 million, respectively. For the nine months ended January 26, 2018, charges included $12 million recognized within *cost of products sold* and $4 million recognized within *selling, general and administrative expense* in the consolidated statements of income.

7. Financial Instruments

Debt Securities

The Company holds investments in marketable debt securities that are classified and accounted for as available-for-sale and are remeasured on a recurring basis. For information regarding the valuation techniques and inputs used in the fair value measurements, refer to Note 1 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended April 27, 2018.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

The following tables summarize the Company's investments in available-for-sale debt securities by significant investment category and the related consolidated balance sheet classification at January 25, 2019 and April 27, 2018:

	January 25, 2019					
	Valuation				Balance Sheet Classification	
(in millions)	Cost	Unrealized Gains	Unrealized Losses	Fair Value	Investments	Other Assets
Level 1:						
U.S. government and agency securities	$ 523	$ —	$ (15)	$ 508	$ 508	$ —
Level 2:						
Corporate debt securities	3,259	3	(60)	3,202	3,202	—
U.S. government and agency securities	841	—	(14)	827	827	—
Mortgage-backed securities	464	1	(28)	437	437	—
Non-U.S. government and agency securities	5	—	—	5	5	—
Other asset-backed securities	464	—	(4)	460	460	—
Total Level 2	5,033	4	(106)	4,931	4,931	—
Level 3:						
Auction rate securities	47	—	(3)	44	—	44
Total available-for-sale debt securities	$ 5,603	$ 4	$ (124)	$ 5,483	$ 5,439	$ 44

	April 27, 2018					
	Valuation				Balance Sheet Classification	
(in millions)	Cost	Unrealized Gains	Unrealized Losses	Fair Value	Investments	Other Assets
Level 1:						
U.S. government and agency securities	$ 732	$ —	$ (26)	$ 706	$ 706	$ —
Level 2:						
Corporate debt securities	4,179	20	(75)	4,124	4,124	—
U.S. government and agency securities	848	—	(24)	824	824	—
Mortgage-backed securities	725	2	(34)	693	693	—
Non-U.S. government and agency securities	74	—	(1)	73	73	—
Other asset-backed securities	358	—	(2)	356	356	—
Total Level 2	6,184	22	(136)	6,070	6,070	—
Level 3:						

Auction rate securities	47	—	(3)	44	—	44
Total available-for-sale debt securities	$ 6,963	$ 22	$ (165)	$ 6,820	$ 6,776	$ 44

The following tables present the gross unrealized losses and fair values of the Company's available-for-sale debt securities that have been in a continuous unrealized loss position deemed to be temporary, aggregated by investment category at January 25, 2019 and April 27, 2018:

	January 25, 2019			
	Less than 12 months		More than 12 months	
(in millions)	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. government and agency securities	$ 42	$ —	$ 812	$ (29)
Corporate debt securities	1,543	(21)	1,168	(39)
Mortgage-backed securities	87	(1)	287	(27)
Other asset-backed securities	313	(3)	81	(1)
Auction rate securities	—	—	44	(3)
Total	$ 1,985	$ (25)	$ 2,392	$ (99)

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

	April 27, 2018			
	Less than 12 months		More than 12 months	
(in millions)	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. government and agency securities	$ 762	$ (33)	$ 374	$ (17)
Corporate debt securities	2,620	(58)	272	(17)
Mortgage-backed securities	442	(15)	102	(19)
Non-U.S. government and agency securities	32	—	36	(1)
Other asset-backed securities	238	(1)	63	(1)
Auction rate securities	—	—	44	(3)
Total	$ 4,094	$ (107)	$ 891	$ (58)

The following table presents the unobservable inputs utilized in the fair value measurement of the auction rate securities classified as Level 3 at January 25, 2019:

	Valuation Technique	Unobservable Input	Range (Weighted Average)
Auction rate securities	Discounted cash flow	Years to principal recovery	2 yrs. - 12 yrs. (3 yrs.)
		Illiquidity premium	6%

The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. The Company's policy is to recognize transfers into and out of levels within the fair value hierarchy at the end of the fiscal quarter in which the actual event or change in circumstances that caused the transfer occurs. There were no transfers between Level 1, Level 2, or Level 3 during the three and nine months ended January 25, 2019 and January 26, 2018. When a determination is made to classify an asset or liability within Level 3, the determination is based upon the significance of the unobservable inputs to the overall fair value measurement.

There were no purchases, sales, settlements, or gains or losses recognized in earnings or other comprehensive income for available-for-sale securities classified as Level 3 during the three and nine months ended January 25, 2019 and January 26, 2018.

Activity related to the Company's debt securities portfolio is as follows:

	Three months ended		Nine months ended	
(in millions)	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Proceeds from sales	$ 1,301	$ 667	$ 3,217	$ 2,618
Gross realized gains	9	3	17	22
Gross realized losses	(36)	(2)	(55)	(16)

Credit losses represent the difference between the present value of cash flows expected to be collected on certain mortgage-backed securities and auction rate securities and the amortized cost of these securities. Based on the Company's assessment of the credit quality of the underlying collateral and credit support available to each of the remaining securities in which the Company is invested, the Company believes it has recognized all necessary other-than-temporary impairments, as the Company does not have the intent to sell, nor is it more likely than not that the Company will be required to sell, before recovery of the amortized cost.

At January 25, 2019 and April 27, 2018, the credit loss portion of other-than-temporary impairments on debt securities was not significant. The total reductions of available-for-sale debt securities sold during the three and nine months ended January 25, 2019 and January 26, 2018 were not significant.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

The January 25, 2019 balance of available-for-sale debt securities by contractual maturity is shown in the following table. Within the table, maturities of mortgage-backed securities have been allocated based upon timing of estimated cash flows assuming no change in the current interest rate environment. Actual maturities may differ from contractual maturities because the issuers of the securities may have the right to prepay obligations without prepayment penalties.

(in millions)	January 25, 2019
Due in one year or less	$ 1,139
Due after one year through five years	1,867
Due after five years through ten years	2,358
Due after ten years	119
Total	$ 5,483

Equity Securities, Equity Method Investments, and Other Investments

The Company holds investments in equity securities with readily determinable fair values, equity investments without readily determinable fair values, investments accounted for under the equity method, and other investments.

Effective April 28, 2018, the Company adopted accounting standards update (ASU) 2016-01, which requires equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income. As a result of the adoption, the Company reclassified $47 million from *accumulated other comprehensive loss* to the opening balance of *retained earnings* as of April 28, 2018. The Company uses quoted market prices to determine the fair value of equity securities with readily determinable fair values. For equity investments without readily determinable fair values that do not qualify for the practical expedient to estimate fair value using the net asset value per share or its equivalent, the Company has elected to measure these investments at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. This election is made for each investment separately and is reassessed at each reporting period as to whether the investment continues to qualify for this election. Additionally, at each reporting period, the Company makes a qualitative assessment considering impairment indicators to evaluate whether the investment is impaired.

Equity securities with readily determinable fair values are included within Level 1 of the fair value hierarchy, as they are measured using quoted market prices. Equity method investments and investments without readily determinable fair values, as described above, are included within Level 3 of the fair value hierarchy due to the use of significant unobservable inputs to determine fair value. To determine the fair value of these investments, the Company uses all pertinent financial information available related to the investees, including financial statements, market participant valuations from recent and proposed equity offerings, and other third-party data.

The following table summarizes the Company's equity and other investments at January 25, 2019, which are classified as *other assets* in the consolidated balance sheets:

(in millions)	January 25, 2019
Investments with readily determinable fair values (marketable equity securities)	$ 20
Investments without readily determinable fair values	240

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Equity method and other investments	70
Total equity and other investments	$ 330

Prior to the adoption of ASU 2016-01, marketable equity securities were classified as available-for-sale and measured at fair value with unrealized changes recognized in accumulated other comprehensive income (AOCI), net of deferred taxes. Gains and losses on available-for-sale marketable equity securities were recognized in net income when realized. The Company also accounted for certain investments without quoted market prices under the cost method of accounting.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

The following table summarizes the values of the Company's equity and other investments by significant investment category and the related consolidated balance sheet classification at April 27, 2018:

	Valuation				Balance Sheet Classification	
(in millions)	Cost	Unrealized Gains	Unrealized Losses	Fair Value	Investments	Other Assets
Available-for-sale securities						
Level 1:						
Marketable equity securities	$ 63	$ 99	$ —	$ 162	$ —	$ 162
Level 2:						
Debt funds	739	—	(154)	585	585	—
Investments measured at net asset value[1]:						
Debt funds	199	—	(2)	197	197	—
Total available-for-sale equity securities	1,001	99	(156)	944	782	162
Cost method, equity method, and other investments:						
Level 3:						
Cost method, equity method, and other investments	353	—	—	N/A	—	353
Total equity and other investments	$ 1,354	$ 99	$ (156)	$ 944	$ 782	$ 515

(1) Certain investments that are measured at the net asset value per share (or its equivalent) as a practical expedient are excluded from the fair value hierarchy. The fair value amounts presented herein are intended to permit reconciliation to the consolidated balance sheets.

The table below includes activity related to the Company's portfolio of equity and other investments. Gains and losses on equity and other investments are recognized in *other non-operating (income) expense, net* in the consolidated statements of income.

	Three months ended		Nine months ended	
(in millions)	January 25, 2019	January 26, 2018[1]	January 25, 2019	January 26, 2018[1]
Proceeds from sales	$ 33	$ 39	$ 941	$ 442
Gross gains	8	8	131	15
Gross losses	(1)	—	(30)	(1)
Impairment losses recognized	—	(227)	(12)	(228)

(1) Gains and losses for the three and nine months ended January 26, 2018 represent realized amounts.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Net gains recognized during the three months ended January 25, 2019 were $7 million, comprised of $1 million net realized gains on equity and other investments sold during the period and $6 million of net unrealized gains on equity and other investments still held at January 25, 2019. Net gains recognized during the nine months ended January 25, 2019 were $101 million, comprised of $71 million of net realized gains on equity and other investments sold during the period and $30 million of net unrealized gains on equity and other investments still held at January 25, 2019.

During the three months ended January 26, 2018, the Company received bids from potential buyers and investors for some or all of its ownership in a portfolio of selected investments, which indicated that the fair values of certain of the underlying cost and equity method investments in the portfolio may be below the respective carrying values. The Company determined that the decline in the fair values was other-than-temporary given the uncertainty regarding the Company's intent to hold the investments for a period of time that would be sufficient to recover the carrying values. As a result, the Company recognized impairment charges of $227 million during the three and nine months ended January 26, 2018, which were recognized in *other non-operating (income) expense, net* in the consolidated statements of income. The fair values of the investments were determined based on Level 3 inputs. The carrying values of the investments prior to recognizing the impairment charges was $317 million. There were no other significant impairments charges recognized during the three and nine months ended January 26, 2018 and January 25, 2019.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

8. Financing Arrangements

Commercial Paper

The Company maintains a commercial paper program that allows the Company to have a maximum of $3.5 billion in commercial paper outstanding. No commercial paper was outstanding at January 25, 2019, as compared to $698 million at April 27, 2018. There was no commercial paper activity during the three months ended January 25, 2019. During the nine months ended January 25, 2019, the weighted average original maturity of the commercial paper outstanding was approximately 28 days, and the weighted average interest rate was 2.10 percent. The issuance of commercial paper reduces the amount of credit available under the Company's existing Credit Facility, as defined below.

Line of Credit

On December 12, 2018, Medtronic Global Holdings S.C.A. (Medtronic Luxco), as borrower, entered into an amended and restated credit agreement (Credit Facility), by and among Medtronic, Medtronic, Inc., Medtronic Luxco, the lenders from time to time party thereto and Bank of America, N.A., as administrative agent and issuing bank, which expires in December 2023. The Credit Facility replaces the previous credit agreement dated November 7, 2014 and effective as of January 26, 2015.

The Credit Facility provides for a $3.5 billion five-year unsecured revolving credit facility, subject to two one-year extension options. The commitments are intended to be used for general corporate purposes, including to backstop the Company's $3.5 billion commercial paper program described above. The Company and Medtronic, Inc. have guaranteed the obligations of the borrowers under the Credit Facility, and Medtronic Luxco will also guarantee the obligations of any designated borrower. The Credit Facility includes a multi-currency borrowing feature for certain specified foreign currencies. No amounts were outstanding under the original and amended credit facilities at January 25, 2019 and April 27, 2018.

Interest rates on advances under the Credit Facility are based on the Company's long-term debt ratings, assigned by Standard & Poor's Ratings Services and Moody's Investors Service. Facility fees are payable on the Credit Facility and are determined in the same manner as the interest rates. The agreement also contains customary covenants, all of which the Company was in compliance with at January 25, 2019.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Debt Obligations

The Company's debt obligations consisted of the following:

(in millions)	Maturity by Fiscal Year	January 25, 2019	April 27, 2018
Current debt obligations	2019 - 2020	$ 1,356	$ 2,058
Long-term debt			
Floating rate five-year 2015 senior notes	2020	500	500
2.500 percent five-year 2015 senior notes	2020	2,500	2,500
4.200 percent ten-year 2010 CIFSA senior notes	2021	600	600
4.125 percent ten-year 2011 senior notes	2021	500	500
3.150 percent seven-year 2015 senior notes	2022	2,500	2,500
3.125 percent ten-year 2012 senior notes	2022	675	675
3.200 percent ten-year 2012 CIFSA senior notes	2023	650	650
2.750 percent ten-year 2013 senior notes	2023	530	530
2.950 percent ten-year 2013 CIFSA senior notes	2024	310	310
3.625 percent ten-year 2014 senior notes	2024	850	850
3.500 percent ten-year 2015 senior notes	2025	4,000	4,000
3.350 percent ten-year 2017 senior notes	2027	850	850
4.375 percent twenty-year 2015 senior notes	2035	2,382	2,382
6.550 percent thirty-year 2008 CIFSA senior notes	2038	374	374
6.500 percent thirty-year 2009 senior notes	2039	300	300
5.550 percent thirty-year 2010 senior notes	2040	500	500
4.500 percent thirty-year 2012 senior notes	2042	400	400
4.000 percent thirty-year 2013 senior notes	2043	325	325
4.625 percent thirty-year 2014 senior notes	2044	650	650
4.625 percent thirty-year 2015 senior notes	2045	4,150	4,150
Bank borrowings	2020 - 2022	94	125
Debt premium, net	2020 - 2045	108	120
Capital lease obligations	2020 - 2025	21	21
Interest rate swaps	2021 - 2022	—	(6)
Deferred financing costs	2020 - 2045	(95)	(107)

Long-term debt	$ 23,674	$ 23,699

Senior Notes

The Company has outstanding unsecured senior debt obligations, described both as senior notes and current debt obligations in the table above (collectively, the Senior Notes). The Senior Notes rank equally with all other unsecured and unsubordinated indebtedness of the Company. The indentures under which the Senior Notes were issued contain customary covenants, all of which the Company remained in compliance with at January 25, 2019. For additional information regarding the terms of these agreements, refer to Note 8 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended April 27, 2018.

On February 20, 2019, the Company announced the commencement of a cash tender offer for up to $5.0 billion of certain of our outstanding Senior Notes. The tender offer will expire on March 19, 2019 unless extended or terminated. The tender offer is subject to a number of conditions, including the condition that the Company receives net proceeds from one or more debt financings sufficient to fund the purchase of tendered notes.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Financial Instruments Not Measured at Fair Value

At January 25, 2019, the estimated fair value of the Company's Senior Notes was $25.2 billion compared to a principal value of $24.5 billion. At April 27, 2018, the estimated fair value was $25.1 billion compared to a principal value of $24.5 billion. The fair value was estimated using quoted market prices for the publicly registered Senior Notes, which are classified as Level 2 within the fair value hierarchy. The fair values and principal values consider the terms of the related debt and exclude the impacts of debt discounts and hedging activity.

9. Derivatives and Currency Exchange Risk Management

The Company uses operational and economic hedges, as well as currency exchange rate derivative contracts and interest rate derivative instruments, to manage the impact of currency exchange and interest rate changes on earnings and cash flows. In addition, the Company uses cross currency interest rate swaps to manage currency risk related to certain debt. In order to minimize earnings and cash flow volatility resulting from currency exchange rates changes, the Company enters into derivative instruments, principally forward currency exchange rate contracts. These contracts are designed to hedge anticipated foreign currency transactions and changes in the value of specific assets and liabilities. At inception of the contract, the derivative is designated as either a freestanding derivative or a cash flow hedge. The cash flows related to all of the Company's derivative instruments are reported as operating activities in the consolidated statement of cash flows. The primary currencies of the derivative instruments are the Euro, Japanese Yen, and British Pound. The Company does not enter into currency exchange rate derivative contracts for speculative purposes. The gross notional amount of all currency exchange rate derivative instruments outstanding was $12.2 billion and $11.5 billion at January 25, 2019 and April 27, 2018, respectively.

The information that follows explains the various types of derivatives and financial instruments used by the Company, reasons the Company uses such instruments, and the impact such instruments have on the Company's consolidated balance sheets and statements of income.

Freestanding Derivative Contracts

Freestanding derivative contracts are used to offset the Company's exposure to the change in value of specific foreign-currency-denominated assets and liabilities and to offset variability of cash flows associated with forecasted transactions denominated in foreign currencies. The gross notional amount of these contracts outstanding was $5.1 billion and $5.2 billion at January 25, 2019 and April 27, 2018 , respectively. The Company's freestanding currency exchange rate contracts are not designated as hedges, and therefore, changes in the value of these contracts are recognized in earnings, thereby offsetting the current earnings effect of the related change in value of foreign-currency-denominated assets, liabilities, and cash flows.

The Company also entered into total return swaps in fiscal year 2018, which are used to hedge the liability of a non-qualified deferred compensation plan. The gross notional amount of the Company's total return swaps outstanding was $174 million and $210 million at January 25, 2019 and April 27, 2018, respectively. The Company's total return swaps are not designated as hedges, and therefore, changes in the value of these instruments are recognized in earnings.

The amounts and classification of the gains (losses) in the consolidated statements of income related to derivative instruments not designated as hedging instruments for the three and nine months ended January 25, 2019 and January 26, 2018 were as follows:

		Three months ended		Nine months ended	
(in millions)	**Classification**	**January 25, 2019**	**January 26, 2018**	**January 25, 2019**	**January 26, 2018**

Currency exchange rate contracts	Other operating expense, net	$ (30)	$ (181)	$ 171	$ (318)
Total return swaps	Other operating expense, net	—	23	—	38
Total		$ (30)	$ (158)	$ 171	$ (280)

Cash Flow Hedges

Currency Exchange Rate Risk

Forward contracts designated as cash flow hedges are designed to hedge the variability of cash flows associated with forecasted transactions denominated in a foreign currency that will take place in the future. For derivative instruments that are designated and qualify as a cash flow hedge, the effective portion of the gain or loss on the derivative instrument is reported as a component of *accumulated other comprehensive loss*. The effective portion of the gain or loss on the derivative instrument is reclassified into earnings and is included in *other operating expense, net* in the consolidated statements of income in the same period or periods during which the hedged transaction affects earnings.

No gains or losses relating to ineffectiveness of cash flow hedges were recognized in earnings during the three and nine months ended January 25, 2019 and January 26, 2018. No components of the hedge contracts were excluded in the measurement of hedge ineffectiveness, and no hedges were derecognized or discontinued during the three and nine months ended January 25, 2019 and January 26, 2018. The gross notional amount of these contracts, designated as cash flow hedges, outstanding was $7.0 billion and $6.3 billion at January 25, 2019 and April 27, 2018, respectively, and will mature within the subsequent three-year period.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

The amounts of the gains (losses) recognized in the consolidated statements of income related to derivative instruments designated as cash flow hedges for the three and nine months ended January 25, 2019 and January 26, 2018 were as follows:

		Three months ended		Nine months ended	
(in millions)	Classification	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Currency exchange rate contracts	Other operating expense, net	$ 48	$ (11)	$ 56	$ 1

The amount of the gains (losses) recognized in AOCI related to the effective portion of currency exchange rate contract derivative instruments designated as cash flow hedges for the three and nine months ended January 25, 2019 and January 26, 2018 were as follows:

	Three months ended		Nine months ended	
(in millions)	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Currency exchange rate contracts	$ 25	$ (287)	$ 469	$ (507)

Forecasted Debt Issuance Interest Rate Risk

Forward starting interest rate derivative instruments designated as cash flow hedges are designed to manage the exposure to interest rate volatility with regard to future issuances of fixed-rate debt. The effective portion of the gains or losses on forward starting interest rate derivative instruments that are designated and qualify as cash flow hedges is reported as a component of accumulated other comprehensive loss. Beginning in the period in which the planned debt issuance occurs and the related derivative instruments are terminated, the effective portion of the gains or losses are then reclassified into interest expense over the term of the related debt. Any portion of the gains or losses that is determined to be ineffective is immediately recognized in interest expense. For the three and nine months ended January 25, 2019, the reclassifications of the effective portion of net gains (losses) on forward starting interest rate derivative instruments from accumulated other comprehensive loss to interest expense were not significant.

The Company had $110 million and $(207) million at January 25, 2019 and April 27, 2018, respectively, in after-tax net unrealized gains (losses) associated with cash flow hedging instruments recorded in *accumulated other comprehensive loss*. The Company expects that $114 million of after-tax net unrealized gains at January 25, 2019 will be recognized in the consolidated statements of income over the next 12 months.

Fair Value Hedges

Interest rate derivative instruments designated as fair value hedges are designed to manage the exposure to interest rate movements and to reduce borrowing costs by converting fixed-rate debt into floating-rate debt. Under these agreements, the Company agrees to exchange, at specified intervals, the difference between fixed and floating interest amounts calculated by reference to an agreed-upon notional principal amount.

Changes in the fair value of the derivative instruments are recognized in *interest expense*, and are offset by changes in the fair value of the underlying debt instrument. The gains (losses) from terminated interest rate swap agreements are recognized in *long-term debt*, increasing (decreasing) the outstanding balances of the debt, and amortized as a reduction of (addition to) *interest expense* over the remaining life of the related debt.

At both January 25, 2019 and April 27, 2018, the Company had interest rate swaps in gross notional amounts of $1.2 billion, designated as fair value hedges of underlying fixed-rate senior note obligations, including the Company's $500 million 4.125 percent 2011 Senior Notes due fiscal year 2021 and the $675 million 3.125 percent 2012 Senior Notes due fiscal year 2022.

At January 25, 2019, the market value of outstanding interest rate swap agreements was in a net zero position, as compared to a net unrealized loss of $6 million at April 27, 2018. The amounts were recorded in *other liabilities*, with the offsets recorded in *long-term debt* on the consolidated balance sheets.

No significant hedge ineffectiveness was recognized as a result of these fair value hedges for the three and nine months ended January 25, 2019 and January 26, 2018. In addition, the Company did not recognize any gains or losses during the three and nine months ended January 25, 2019 and January 26, 2018 on firm commitments that no longer qualify as fair value hedges.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Balance Sheet Presentation

The following tables summarize the balance sheet classification and fair value of derivative instruments included in the consolidated balance sheets at January 25, 2019 and April 27, 2018. The fair value amounts are presented on a gross basis, and are segregated between derivatives that are designated and qualify as hedging instruments and those that are not designated and do not qualify as hedging instruments and are further segregated by type of contract within those two categories.

	January 25, 2019			
	Derivative Assets		Derivative Liabilities	
(in millions)	Balance Sheet Classification	Fair Value	Balance Sheet Classification	Fair Value
Derivatives designated as hedging instruments				
Currency exchange rate contracts	Other current assets	$ 169	Other accrued expenses	$ 7
Interest rate contracts	Other assets	7	Other liabilities	7
Currency exchange rate contracts	Other assets	68	Other liabilities	7
Total derivatives designated as hedging instruments		244		21
Derivatives not designated as hedging instruments				
Currency exchange rate contracts	Other current assets	16	Other accrued expenses	25
Total return swap	Other current assets	—	Other accrued expenses	4
Cross currency interest rate contracts	Other current assets	8	Other accrued expenses	3
Cross currency interest rate contracts	Other assets	1	Other liabilities	1
Total derivatives not designated as hedging instruments		25		33
Total derivatives		$ 269		$ 54

	April 27, 2018			
	Derivative Assets		Derivative Liabilities	
(in millions)	Balance Sheet Classification	Fair Value	Balance Sheet Classification	Fair Value
Derivatives designated as hedging instruments				
Currency exchange rate contracts	Other current assets	$ 37	Other accrued expenses	$ 162
Interest rate contracts	Other assets	8	Other liabilities	14
Currency exchange rate contracts	Other assets	11	Other liabilities	51
Total derivatives designated as hedging instruments		56		227
Derivatives not designated as hedging instruments				

Currency exchange rate contracts	Other current assets	31	Other accrued expenses	25
Total return swaps	Other current assets	4	Other accrued expenses	—
Stock warrants	Other assets	21	Other liabilities	—
Cross currency interest rate contracts	Other assets	6	Other liabilities	6
Total derivatives not designated as hedging instruments		62		31
Total derivatives		$ 118		$ 258

The following table provides information by level for the derivative assets and liabilities that are measured at fair value on a recurring basis.

	January 25, 2019		April 27, 2018	
(in millions)	**Level 1**	**Level 2**	**Level 1**	**Level 2**
Derivative assets	$ 253	$ 16	$ 79	$ 39
Derivative liabilities	39	15	238	20

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

The Company has elected to present the fair value of derivative assets and liabilities within the consolidated balance sheets on a gross basis, even when derivative transactions are subject to master netting arrangements and may otherwise qualify for net presentation. The cash flows related to collateral posted and received are reported gross as investing and financing activities, respectively, in the consolidated statements of cash flows.

The following tables provides information as if the Company had elected to offset the asset and liability balances of derivative instruments, netted in accordance with various criteria as stipulated by the terms of the master netting arrangements with each of the counterparties. Derivatives not subject to master netting arrangements are not eligible for net presentation.

	January 25, 2019				
		Gross Amount Not Offset on the Balance Sheet			
(in millions)	Gross Amount of Recorded Assets (Liabilities)	Financial Instruments	Cash Collateral Posted (Received)	Securities Collateral Posted (Received)	Net Amount
Derivative assets:					
Currency exchange rate contracts	$ 253	$ (33)	$ (17)	$ —	$ 203
Interest rate contracts	7	(4)	—	—	3
Cross currency interest rate contracts	9	(1)	—	—	8
	269	(38)	(17)	—	214
Derivative liabilities:					
Currency exchange rate contracts	(39)	31	—	—	(8)
Interest rate contracts	(7)	6	—	—	(1)
Total return swaps	(4)	—	—	—	(4)
Cross currency interest rate contracts	(4)	1	—	—	(3)
	(54)	38	—	—	(16)
Total	$ 215	$ —	$ (17)	$ —	$ 198

	April 27, 2018				
		Gross Amount Not Offset on the Balance Sheet			
(in millions)	Gross Amount of Recorded Assets (Liabilities)	Financial Instruments	Cash Collateral Posted (Received)	Securities Collateral Posted (Received)	Net Amount
Derivative assets:					
Currency exchange rate contracts	$ 79	$ (61)	$ —	$ —	$ 18
Interest rate contracts	8	(6)	—	—	2
Total return swaps	4	—	—	—	4
Stock warrants	21	—	—	—	21

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Cross currency interest rate contracts	6	(4)	—	—	2
	118	(71)	—	—	47
Derivative liabilities:					
Currency exchange rate contracts	(238)	61	—	74	(103)
Interest rate contracts	(14)	6	—	2	(6)
Cross currency interest rate contracts	(6)	4	—	—	(2)
	(258)	71	—	76	(111)
Total	$ (140)	$ —	$ —	$ 76	$ (64)

10. Inventories

Inventory balances, net of reserves, were as follows:

(in millions)	January 25, 2019	April 27, 2018
Finished goods	$ 2,545	$ 2,407
Work in-process	560	496
Raw materials	761	676
Total	$ 3,866	$ 3,579

11. Goodwill and Other Intangible Assets

Goodwill

The following table presents the changes in the carrying amount of goodwill by segment:

(in millions)	Cardiac and Vascular Group	Minimally Invasive Therapies Group	Restorative Therapies Group	Diabetes Group	Total
April 27, 2018	$ 6,791	$ 21,155	$ 9,717	$ 1,880	$ 39,543
Goodwill as a result of acquisitions	—	82	1,254	24	1,360
Currency translation and other	(82)	(691)	(126)	(1)	(900)
January 25, 2019	$ 6,709	$ 20,546	$ 10,845	$ 1,903	$ 40,003

The Company assesses goodwill for impairment annually in the third quarter of the fiscal year and whenever an event occurs or circumstances change that would indicate that the carrying amount may be impaired. Impairment testing for goodwill is performed at the reporting unit level. The test for impairment of goodwill requires the Company to make several estimates about fair value, most of which are based on projected future cash flows. The Company calculates the excess of each reporting unit's fair value over its carrying amount, including goodwill, utilizing a discounted cash flow analysis. The Company did not recognize any goodwill impairment during the three or nine months ended January 25, 2019 or January 26, 2018.

Intangible Assets

The following table presents the gross carrying amount and accumulated amortization of intangible assets:

(in millions)	January 25, 2019 Gross Carrying Amount	January 25, 2019 Accumulated Amortization	April 27, 2018 Gross Carrying Amount	April 27, 2018 Accumulated Amortization
Definite-lived:				
Customer-related	$ 16,950	$ (3,854)	$ 16,949	$ (3,139)
Purchased technology and patents	11,469	(4,464)	11,569	(4,441)
Trademarks and tradenames	570	(320)	822	(569)
Other	88	(55)	94	(52)
Total	$ 29,077	$ (8,693)	$ 29,434	$ (8,201)
Indefinite-lived:				
IPR&D	$ 451		$ 490	

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

The Company assesses definite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an intangible asset (asset group) may not be recoverable. When events or changes in circumstances indicate that the carrying amount of an intangible asset may not be recoverable, the Company calculates the excess of an intangible asset's carrying value over its undiscounted future cash flows. If the carrying value is not recoverable, an impairment loss is recognized based on the amount by which the carrying value exceeds the fair value. The inputs used in the fair value analysis fall within Level 3 of the fair value hierarchy due to the use of significant unobservable inputs to determine fair value. During the three months ended January 25, 2019, the Company recognized $26 million of definite-lived intangible asset charges in connection with business exits within the Restorative Therapies Group segment. During the nine months ended January 25, 2019, the Company recognized $87 million of definite-lived intangible asset charges, including $26 million and $61 million of charges in connection with business exits within the Restorative Therapies Group and Cardiac and Vascular Group segments, respectively. Definite-lived intangible asset charges are recognized in *other operating expense, net* in the consolidated statements of income. The Company did not recognize any definite-lived intangible asset charges during the three or nine months ended January 26, 2018.

The Company assesses indefinite-lived intangibles for impairment annually in the third quarter of the fiscal year and whenever an event occurs or circumstances change that would indicate that the carrying amount may be impaired. During the three and nine months ended January 25, 2019, the Company recognized $21 million of indefinite-lived intangible asset charges, including $11 million in connection with a business exit within the Restorative Therapies Group segment. During the three and nine months ended January 26, 2018, the Company recognized indefinite-lived intangible asset charges of $63 million and $68 million, respectively, including $63 million as the result of the discontinuation of certain IPR&D projects within the Restorative Therapies Group segment. Indefinite-lived intangible asset charges are recognized in *other operating expense, net* in the consolidated statements of income. Due to the nature of IPR&D projects, the Company may experience future delays or failures to obtain regulatory approvals to conduct clinical trials, failures of such clinical trials, delays or failures to obtain required market clearances, other failures to achieve a commercially viable product, or the discontinuation a certain projects, and as a result, may recognize impairment losses in the future.

Amortization Expense

Intangible asset amortization expense for the three and nine months ended January 25, 2019 was $436 million and $1.3 billion, respectively, as compared to $461 million and $1.4 billion for the three and nine months ended January 26, 2018, respectively. Estimated aggregate amortization expense by fiscal year based on the carrying value of definite-lived intangible assets at January 25, 2019, excluding any possible future amortization associated with acquired IPR&D which has not yet met technological feasibility, is as follows:

(in millions)	Amortization Expense
Remaining 2019	$ 437
2020	1,740
2021	1,723
2022	1,683
2023	1,614
2024	1,573

12. Income Taxes

On December 22, 2017, the U.S. government enacted comprehensive tax legislation, commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"), which significantly revises U.S. corporate income taxation by, among other things, lowering the U.S. corporate income tax rate from 35.0 percent to 21.0 percent, broadening the base of taxation,

implementing a territorial tax system, and imposing a repatriation tax on deemed repatriated earnings of foreign subsidiaries. U.S. GAAP requires that the impact of tax legislation be recognized in the period in which the law was enacted. The Company adopted guidance allowing for a measurement period, not to exceed one year, to finalize the accounting for the income tax impacts of the Tax Act. The measurement period closed during the three months ended January 25, 2019.

During the three months ended January 25, 2019, the Company recorded a net benefit of $12 million associated with the transition tax liability and the Tax Act impact to deferred tax assets, liabilities, and valuation allowances. The Company has recorded a cumulative income tax charge associated with the Tax Act totaling $2.5 billion, which is comprised of the following components:

- A $2.4 billion charge associated with the one-time repatriation tax based on post-1986 undistributed earnings and profits not previously subject to U.S. income tax and whether such earnings were held in cash or other specified assets.

- A $118 million charge resulting from the removal of the permanent reinvestment assertion on earnings through April 27, 2018 for entities subject to the one-time repatriation tax.

- A $77 million net benefit associated with the remeasurement of U.S. Federal deferred tax assets, liabilities, and valuation allowances, and impacts from the decrease in the U.S. statutory tax rate.

The Company made the accounting policy election to treat taxes due on U.S. inclusions in taxable income related to Global Intangible Low-Taxed Income (GILTI) as a current period expense when incurred (the "period cost method").

The Company's effective tax rate for the three and nine months ended January 25, 2019 was 7.2 percent and 11.2 percent, respectively, as compared to 235.5 percent and 58.7 percent for the three and nine months ended January 26, 2018, respectively. The decrease in the effective tax rate for the three and nine months ended January 25, 2019, as compared to the corresponding periods in the prior fiscal year, was primarily due to the impacts from U.S. tax reform. Further driving the decrease were the impacts from certain tax adjustments, the gain on the divestiture of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses during the second quarter of fiscal year 2018, the impact from investment losses, the finalization of certain tax returns and audits, the impact from the lapse of federal statutes of limitations, excess tax benefits related to stock-based compensation, and year-over-year changes in operational results by jurisdiction.

Certain Tax Adjustments

During the three months ended January 25, 2019, the net benefit from certain tax adjustments of $64 million, recognized in *income tax provision* in the consolidated statements of income, included the following:

- A net benefit of $12 million associated with the transition tax liability and the Tax Act impact to deferred tax assets, liabilities, and valuation allowances, as noted above.

- A benefit of $32 million related to intercompany legal entity restructuring.

- A net benefit of $20 million associated with the finalization of certain income tax aspects of the divestiture of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses.

During the nine months ended January 25, 2019, the net benefit from certain tax adjustments of $35 million, recognized in *income tax provision* in the consolidated statements of income, included the following:

- A net benefit of $25 million associated with the transition tax liability and the Tax Act impact to deferred tax assets, liabilities, and valuation allowances, as noted above.

- A $32 million benefit of related to intercompany legal entity restructuring.

- A $20 million net benefit associated with the finalization of certain income tax aspects of the divestiture of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses.

- A charge of $42 million related to the recognition of a prepaid tax expense resulting from the reduction in the U.S. statutory tax rate under the Tax Act and the current quarter sale of U.S. manufactured inventory held as of April 27, 2018.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

During the three months ended January 26, 2018, the net charge from certain tax adjustments of $2.2 billion, recognized in *income tax provision* in the consolidated statements of income, included the following:

- A net charge of $2.2 billion associated with U.S. tax reform.

During the nine months ended January 26, 2018, the net charge from certain tax adjustments of $1.9 billion, recognized in *income tax provision* in the consolidated statements of income, included the following:

- A net charge of $2.2 billion associated with U.S. tax reform.
- A net benefit of $398 million associated with the intercompany sales of intellectual property.
- A net charge of $37 million primarily related to the sale of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses.

At January 25, 2019 and April 27, 2018, the Company's gross unrecognized tax benefits were $1.8 billion and $1.7 billion, respectively. In addition, the Company had accrued gross interest and penalties of $192 million at January 25, 2019. If all of the Company's unrecognized tax benefits were recognized, approximately $1.7 billion would impact the Company's effective tax rate. At both January 25, 2019 and April 27, 2018, the total balance of the Company's gross unrecognized tax benefits was recorded as a noncurrent liability within *accrued income taxes* on the consolidated balance sheets. The Company recognizes interest and penalties related to income tax matters within *income tax provision* in the consolidated statements of income and records the liability within either current or noncurrent *accrued income taxes* on the consolidated balance sheets.

Refer to Note 17 to the consolidated financial statements for additional information regarding the status of current tax audits and proceedings.

13. Earnings Per Share

Earnings per share is calculated using the two-class method, as the Company's A Preferred Shares are considered participating securities. Accordingly, earnings are allocated to both ordinary shares and participating securities in determining earnings per ordinary share. Due to the limited number of A Preferred Shares outstanding, this allocation had no effect on ordinary earnings per share; therefore, it is not presented below. Basic earnings per share is computed based on the weighted average number of ordinary shares outstanding. Diluted earnings per share is computed based on the weighted average number of ordinary shares outstanding, increased by the number of additional shares that would have been outstanding had the potentially dilutive ordinary shares been issued, and reduced by the number of shares the Company could have repurchased with the proceeds from issuance of the potentially dilutive shares. Potentially dilutive ordinary shares include stock-based awards granted under stock-based compensation plans and shares committed to be purchased under the employee stock purchase plan.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

The table below sets forth the computation of basic and diluted earnings (loss) per share:

	Three months ended		Nine months ended	
(in millions, except per share data)	**January 25, 2019**	**January 26, 2018**	**January 25, 2019**	**January 26, 2018**
Numerator:				
Net income (loss) attributable to ordinary shareholders	$ 1,269	$ (1,389)	$ 3,459	$ 1,644
Denominator:				
Basic – weighted average shares outstanding	1,342.8	1,354.0	1,348.1	1,357.2
Effect of dilutive securities:				
Employee stock options	6.9	—	7.9	8.1
Employee restricted stock units	3.0	—	3.2	3.4
Other	—	—	0.3	0.2
Diluted – weighted average shares outstanding	1,352.7	1,354.0	1,359.5	1,368.9
Basic earnings (loss) per share	$ 0.95	$ (1.03)	$ 2.57	$ 1.21
Diluted earnings (loss) per share	$ 0.94	$ (1.03)	$ 2.54	$ 1.20

As a result of the net loss for the three months ended January 26, 2018, the Company excluded 10.5 million potentially dilutive common shares from the diluted loss per share calculation. The calculation of weighted average diluted shares outstanding excludes options to purchase approximately 7 million ordinary shares for both the three and nine months ended January 25, 2019, and 10 million and 9 million ordinary shares for the three and nine months ended January 26, 2018, respectively, because their effect would have been anti-dilutive on the Company's earnings per share.

14. Stock-Based Compensation

The following table presents the components and classification of stock-based compensation expense for stock options, restricted stock, and employee stock purchase plan shares recognized for the three and nine months ended January 25, 2019 and January 26, 2018:

	Three months ended		Nine months ended	
(in millions)	**January 25, 2019**	**January 26, 2018**	**January 25, 2019**	**January 26, 2018**
Stock options	$ 11	$ 28	$ 62	$ 105
Restricted stock	43	38	144	145
Employee stock purchase plan	6	6	22	20
Total stock-based compensation expense	$ 60	$ 72	$ 228	$ 270

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Cost of products sold	$ 5	$ 10	$ 23	$ 34
Research and development expense	8	8	29	29
Selling, general, and administrative expense	47	54	176	207
Total stock-based compensation expense	60	72	228	270
Income tax benefits	(8)	(12)	(40)	(69)
Total stock-based compensation expense, net of tax	$ 52	$ 60	$ 188	$ 201

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

15. Retirement Benefit Plans

The Company sponsors various retirement benefit plans, including defined benefit pension plans, post-retirement medical plans, defined contribution savings plans, and termination indemnity plans, covering substantially all U.S. employees and many employees outside the U.S. The net periodic benefit cost of the defined benefit pension plans included the following components for the three and nine months ended January 25, 2019 and January 26, 2018:

	U.S.		Non-U.S.	
	Three months ended		Three months ended	
(in millions)	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Service cost	$ 27	$ 29	$ 15	$ 17
Interest cost	33	29	7	7
Expected return on plan assets	(54)	(51)	(14)	(13)
Amortization of net actuarial loss	19	20	3	4
Plan settlement	—	15	—	—
Net periodic benefit cost	$ 25	$ 42	$ 11	$ 15

	U.S.		Non-U.S.	
	Nine months ended		Nine months ended	
(in millions)	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Service cost	$ 81	$ 87	$ 45	$ 51
Interest cost	99	89	21	21
Expected return on plan assets	(162)	(155)	(42)	(39)
Amortization of net actuarial loss	57	60	9	12
Plan settlement	—	15	—	—
Net periodic benefit cost	$ 75	$ 96	$ 33	$ 45

Components of net periodic benefit cost other than the service component are recognized in *other non-operating (income) expense, net* in the consolidated statements of income.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

16. Accumulated Other Comprehensive Income and Supplemental Equity Disclosure

The following table provides changes in AOCI, net of tax, and by component:

(in millions)	Unrealized (Loss) Gain on Investment Securities	Cumulative Translation Adjustment	Net Change in Retirement Obligations	Unrealized (Loss) Gain on Derivative Financial Instruments	Total Accumulated Other Comprehensive (Loss) Income
April 27, 2018	$ (194)	$ (268)	$ (1,117)	$ (207)	$ (1,786)
Other comprehensive (loss) income before reclassifications	(7)	(1,124)	—	353	(778)
Reclassifications	30	—	65	(36)	59
Other comprehensive income (loss)	23	(1,124)	65	317	(719)
Cumulative effect of change in accounting principle[1]	47	—	—	—	47
January 25, 2019	$ (124)	$ (1,392)	$ (1,052)	$ 110	$ (2,458)

(in millions)	Unrealized (Loss) Gain on Investment Securities	Cumulative Translation Adjustment	Net Change in Retirement Obligations	Unrealized Gain (Loss) on Derivative Financial Instruments	Total Accumulated Other Comprehensive (Loss) Income
April 28, 2017	$ (69)	$ (1,452)	$ (1,129)	$ 37	$ (2,613)
Other comprehensive income (loss) before reclassifications	50	1,559	(38)	(351)	1,220
Reclassifications	(9)	(34)	49	5	11
Other comprehensive income (loss)	41	1,525	11	(346)	1,231
January 26, 2018	$ (28)	$ 73	$ (1,118)	$ (309)	$ (1,382)

(1) Refer to Note 2 to the consolidated financial statements for discussion regarding the adoption of accounting standards during the nine months ended January 25, 2019.

The income tax on gains and losses on investment securities in other comprehensive income before reclassifications during the nine months ended January 25, 2019 and January 26, 2018 was a benefit of $2 million and an expense of $33 million, respectively. During the nine months ended January 25, 2019 and January 26, 2018, realized gains and losses on investment securities reclassified from AOCI were reduced by income taxes of $2 million and $4 million, respectively. When realized, gains and losses on investment securities reclassified from AOCI are recognized within *other non-operating (income) expense, net*. Refer to Note 7 to the consolidated financial statements for additional information.

For the nine months ended January 25, 2019, the income tax benefit on cumulative translation adjustments was $8 million. For the nine months ended January 26, 2018, taxes were not provided on cumulative translation adjustments as substantially all translation adjustments relate to earnings that were intended to be indefinitely reinvested outside the U.S.

The net change in retirement obligations in other comprehensive income includes net amortization of actuarial losses included in net periodic benefit cost. During the nine months ended January 25, 2019, there was no income tax impact on the net change in retirement obligations in other comprehensive income before reclassifications. The income tax on the net change in retirement obligations in other comprehensive income before reclassifications during the nine months ended January 26, 2018 was a benefit of $6 million. During the

nine months ended January 25, 2019 and January 26, 2018, the gains and losses on defined benefit and pension items reclassified from AOCI were reduced by income taxes of $15 million and $21 million, respectively. When realized, net gains and losses on defined benefit and pension items reclassified from AOCI are recognized within *other non-operating (income) expense, net*. Refer to Note 15 to the consolidated financial statements for additional information.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

The income tax on unrealized gains and losses on derivative financial instruments in other comprehensive income before reclassifications during the nine months ended January 25, 2019 and January 26, 2018 was an expense of $116 million and a benefit of $156 million, respectively. During the nine months ended January 25, 2019, gains and losses on derivative financial instruments reclassified from AOCI were reduced by income taxes of $16 million. During the nine months ended January 26, 2018, there was no income tax impact on the gains and losses on derivative financial instruments reclassified from AOCI. When realized, cash flow hedge gains and losses reclassified from AOCI are recognized within *other operating expense, net,* and forward starting interest rate derivative financial instrument gains and losses reclassified from AOCI are recognized within *interest expense.* Refer to Note 9 to the consolidated financial statements for additional information.

The supplemental equity schedule below presents changes in the Company's total shareholders' equity and noncontrolling interests for the nine months ended January 25, 2019 and January 26, 2018.

(in millions)	Total Shareholders' Equity	Noncontrolling Interests	Total Equity
April 27, 2018	$ 50,720	$ 102	$ 50,822
Net income	3,459	9	3,468
Other comprehensive loss	(719)	(3)	(722)
Dividends to shareholders	(2,022)	—	(2,022)
Issuance of shares under stock purchase and award plans	826	—	826
Repurchase of ordinary shares	(2,663)	—	(2,663)
Stock-based compensation	228	—	228
Changes to noncontrolling ownership interests	—	4	4
January 25, 2019	$ 49,829	$ 112	$ 49,941

(in millions)	Total Shareholders' Equity	Noncontrolling Interests	Total Equity
April 28, 2017	$ 50,294	$ 122	$ 50,416
Net income (loss)	1,644	(14)	1,630
Other comprehensive income	1,231	—	1,231
Dividends to shareholders	(1,870)	—	(1,870)
Issuance of shares under stock purchase and award plans	266	—	266
Repurchase of ordinary shares	(1,897)	—	(1,897)
Stock-based compensation	270	—	270
Cumulative effect of change in accounting principle	296	—	296
Changes to noncontrolling ownership interests	—	(2)	(2)
January 26, 2018	$ 50,234	$ 106	$ 50,340

Cash dividends declared and paid per ordinary share were $0.50 for each quarter in fiscal year 2019 and $0.46 for each quarter in fiscal year 2018.

17. Commitments and Contingencies

Legal Matters

The Company and its affiliates are involved in a number of legal actions involving product liability, intellectual property and commercial disputes, shareholder related matters, environmental proceedings, income tax disputes, and governmental proceedings and investigations, including those described below. With respect to governmental proceedings and investigations, like other companies in our industry, the Company is subject to extensive regulation by national, state and local governmental agencies in the United States and in other jurisdictions in which the Company and its affiliates operate. As a result, interaction with governmental agencies is ongoing. The Company's standard practice is to cooperate with regulators and investigators in responding to inquiries. The outcomes of legal actions are not within the Company's complete control and may not be known for prolonged periods of time. In some actions, the enforcement agencies or private claimants seek damages, as well as other civil or criminal remedies (including injunctions barring the sale of products that are the subject of the proceeding), that could require significant expenditures, result in lost revenues, or limit the Company's ability to conduct business in the applicable jurisdictions.

The Company records a liability in the consolidated financial statements on an undiscounted basis for loss contingencies related to legal actions when a loss is known or considered probable and the amount may be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not known or probable, and may be reasonably estimated, the estimated loss or range of loss is disclosed. When determining the estimated loss or range of loss, significant judgment is required. Estimates of probable losses resulting from litigation and governmental proceedings involving the Company are inherently difficult to predict, particularly when the matters are in early procedural stages, with incomplete scientific facts or legal discovery, involve unsubstantiated or indeterminate claims for damages, potentially involve penalties, fines or punitive damages, or could result in

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

a change in business practice. At January 25, 2019 and April 27, 2018, accrued litigation was approximately $0.8 billion and $0.9 billion, respectively. The ultimate cost to the Company with respect to accrued litigation could be materially different than the amount of the current estimates and accruals and could have a material adverse impact on the Company's consolidated earnings, financial position, and/or cash flows. The Company includes accrued litigation in *other accrued expenses* and *other liabilities* on the consolidated balance sheets. While it is not possible to predict the outcome for most of the legal matters discussed below, the Company believes it is possible that the costs associated with these matters could have a material adverse impact on the Company's consolidated earnings, financial position, and/or cash flows.

Product Liability Matters

Sprint Fidelis

In 2007, a putative class action was filed in the Ontario Superior Court of Justice in Canada seeking damages for personal injuries allegedly related to the Company's Sprint Fidelis family of defibrillation leads. On October 20, 2009, the court certified a class proceeding but denied class certification on plaintiffs' claim for punitive damages. Pretrial proceedings are underway. The Company has recognized an expense for probable and estimable damages related to this matter, and accrued expenses for this matter are included within accrued litigation as discussed above.

INFUSE Litigation

The Company estimated law firms representing approximately 6,000 claimants asserted or intended to assert personal injury claims against Medtronic in the U.S. state and federal courts involving the INFUSE bone graft product. As of June 1, 2017, the Company had reached agreements to settle substantially all of these claims, resolving this litigation. The Company's accrued expenses for this matter are included within accrued litigation as discussed above.

Pelvic Mesh Litigation

The Company is currently involved in litigation in various state and federal courts against manufacturers of pelvic mesh products alleging personal injuries resulting from the implantation of those products. Two subsidiaries of Covidien supplied pelvic mesh products to one of the manufacturers, C.R. Bard (Bard), named in the litigation. The litigation includes a federal multi-district litigation in the U.S. District Court for the Northern District of West Virginia and cases in various state courts and jurisdictions outside the U.S. Generally, complaints allege design and manufacturing claims, failure to warn, breach of warranty, fraud, violations of state consumer protection laws and loss of consortium claims. In fiscal year 2016, Bard paid the Company $121 million towards the settlement of 11,000 of these claims. In May 2017, the agreement with Bard was amended to extend the terms to apply to up to an additional 5,000 claims. That agreement does not resolve the dispute between the Company and Bard with respect to claims that do not settle, if any. As part of the agreement, the Company and Bard agreed to dismiss without prejudice their pending litigation with respect to Bard's obligation to defend and indemnify the Company. The Company estimates law firms representing approximately 15,800 claimants have asserted or may assert claims involving products manufactured by Covidien's subsidiaries. As of February 1, 2019, the Company had reached agreements to settle approximately 15,100 of these claims. The Company's accrued expenses for this matter are included within accrued litigation as discussed above.

Patent Litigation

Ethicon

On December 14, 2011, Ethicon filed an action against Covidien in the U.S. District Court for the Southern District of Ohio, alleging patent infringement and seeking monetary damages and injunctive relief. On January 22, 2014, the district court entered summary judgment in Covidien's favor, and the majority of this ruling was affirmed by the Federal Circuit on August 7, 2015. Following appeal, the case was remanded back to the District Court with respect to one patent. On January 21, 2016, Covidien filed a second action in the U.S. District Court for the Southern District of Ohio, seeking a declaration of non-infringement with respect to a second set of patents held by Ethicon. The court consolidated this second action with the remaining patent issues from the first action. Following consolidation of the cases, Ethicon dismissed six of the asserted patents, leaving a single asserted patent. In addition to claims of non-infringement, the Company asserts an affirmative defense of invalidity. The Company has not recognized an expense related to damages in connection with this matter, because any potential loss is not currently probable or reasonably estimable under U.S. GAAP. Additionally, the Company is unable to reasonably estimate the range of loss, if any, that may result from this matter.

Sasso

The Company is involved in litigation in Indiana relating to certain patent and royalty disputes with Dr. Sasso under agreements originally entered into in 1999 and 2001. On November 28, 2018, a jury in Indiana state court returned a verdict against the

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Company for approximately $112 million. The Company has strong arguments to appeal the verdict and has filed post-trial motions and appeals with the appropriate appellate courts. The Company has not recognized an expense in connection with this matter because it does not currently believe a loss is probable under U.S. GAAP.

Shareholder Related Matters

Covidien Acquisition

On July 2, 2014, Lewis Merenstein filed a putative shareholder class action in Hennepin County, Minnesota, District Court seeking to enjoin the then-potential acquisition of Covidien. The lawsuit named Medtronic, Inc., Covidien, and each member of the Medtronic, Inc. Board of Directors at the time as defendants, and alleged that the directors breached their fiduciary duties to shareholders with regard to the then-potential acquisition. On August 21, 2014, Kenneth Steiner filed a putative shareholder class action in Hennepin County, Minnesota, District Court, also seeking an injunction to prevent the potential Covidien acquisition. In September 2014, the *Merenstein* and *Steiner* matters were consolidated and in December 2014, the plaintiffs filed a preliminary injunction motion seeking to enjoin the Covidien transaction. On March 20, 2015, the District Court issued an order and opinion granting Medtronic's motion to dismiss the case. In May of 2015, the plaintiffs filed an appeal, and, in January of 2016, the Minnesota State Court of Appeals affirmed in part, and reversed in part. On April 19, 2016 the Minnesota Supreme Court granted the Company's petition to review the issue of whether most of the original claims are properly characterized as direct or derivative under Minnesota law. In August of 2017, the Minnesota Supreme Court affirmed the decision of the Minnesota State Court of Appeals, sending the matter back to the trial court for further proceedings, which are ongoing. The Company has not recognized an expense related to damages in connection with this matter, because any potential loss is not currently probable or reasonably estimable under U.S. GAAP. Additionally, the Company is unable to reasonably estimate the range of loss, if any, that may result from these matters.

HeartWare

On January 22, 2016, the St. Paul Teachers' Retirement Fund Association filed a putative class action complaint (the "Complaint") in the United States District Court for the Southern District of New York against HeartWare on behalf of all persons and entities who purchased or otherwise acquired shares of HeartWare from June 10, 2014 through January 11, 2016 (the "Class Period"). The Complaint was amended on June 29, 2016 and claims HeartWare and one of its executives violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making false and misleading statements about, among other things, HeartWare's response to a June 2014 U.S. FDA warning letter, the development of the Miniaturized Ventricular Assist Device (MVAD) System and the proposed acquisition of Valtech Cardio Ltd. The Complaint seeks to recover damages on behalf of all purchasers or acquirers of HeartWare's stock during the Class Period. In August of 2016, the Company acquired HeartWare. In October of 2018, the parties reached an agreement to settle this matter, and in January 2019, the settlement amount was deposited into a qualified settlement fund to be distributed following final court approval.

Environmental Proceedings

The Company is involved in various stages of investigation and cleanup related to environmental remediation matters at a number of sites. These projects relate to a variety of activities, including removal of solvents, metals and other hazardous substances from soil and groundwater. The ultimate cost of site cleanup and timing of future cash flows is difficult to predict given uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations, and alternative cleanup methods.

The Company is a successor to a company which owned and operated a chemical manufacturing facility in Orrington, Maine from 1967 until 1982, and is responsible for the costs of completing an environmental site investigation as required by the Maine Department of Environmental Protection (MDEP). MDEP served a compliance order on Mallinckrodt LLC and U.S. Surgical Corporation, subsidiaries of Covidien, in December 2008, which included a directive to remove a significant volume of soils at the site. After a hearing on

the compliance order before the Maine Board of Environmental Protection (Maine Board) to challenge the terms of the compliance order, the Maine Board modified the MDEP order and issued a final order requiring removal of two landfills, capping of the remaining three landfills, installation of a groundwater extraction system and long-term monitoring of the site and the three remaining landfills.

The Company has proceeded with implementation of the investigation and remediation at the site in accordance with the MDEP order as modified by the Maine Board order.

Since the early 2000s, the Company or its predecessors have also been involved in a lawsuit filed in the U.S. District Court for the District of Maine by the Natural Resources Defense Council and the Maine People's Alliance. Plaintiffs sought an injunction requiring the Company's predecessor to conduct extensive studies of mercury contamination of the Penobscot River and Bay and options for remediating such contamination, and to perform appropriate remedial activities, if necessary.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Following a trial in March 2002, the Court held that conditions in the Penobscot River and Bay may pose an imminent and substantial endangerment and that the Company's predecessor was liable for the cost of performing a study of the River and Bay. Following a second trial in June 2014, the Court ordered that further engineering study and engineering design work was needed to determine the nature and extent of remediation in the Penobscot River and Bay. The Court also appointed an engineering firm to conduct such studies and issue a report on potential remediation alternatives. In connection with these proceedings, reports have been produced including a variety of cost estimates for a variety of potential remedial options. A third trial to determine the course of remediation to be pursued is scheduled to occur in October of 2019.

The Company's accrued expenses for environmental proceedings are included within accrued litigation as discussed above.

Government Matters

Since 2017, the Company has been responding to requests from the Department of Justice and U.S. Department of Health and Human Services for information about business practices relating to a neurovascular product developed and first marketed by ev3 and Covidien. The Company has provided information in response to these requests and is cooperating with the inquiry. The Company has not recognized an expense in connection with any ongoing investigation, because any such potential loss is not currently probable or reasonably estimable under U.S. GAAP. Additionally, the Company is unable to reasonably estimate the range of loss, if any, that may result from the ongoing information requests.

Income Taxes

In March 2009, the IRS issued its audit report on Medtronic, Inc. for fiscal years 2005 and 2006. Medtronic, Inc. reached agreement with the IRS on some, but not all matters related to these fiscal years. The remaining unresolved issue for fiscal years 2005 and 2006 relates to the allocation of income between Medtronic, Inc. and its wholly-owned subsidiary operating in Puerto Rico, which is one of the Company's key manufacturing sites. The U.S. Tax Court reviewed this dispute, and on June 9, 2016, issued its opinion with respect to the allocation of income between the parties for fiscal years 2005 and 2006. The U.S. Tax Court generally rejected the IRS's position, but also made certain modifications to the Medtronic, Inc. tax returns as filed. On April 21, 2017, the IRS filed their Notice of Appeal to the U.S. Court of Appeals for the 8th Circuit regarding the Tax Court Opinion. Oral argument for the Appeal occurred on March 14, 2018. The 8th Circuit Court of Appeals issued their opinion on August 16, 2018, and remanded the case back to the U.S. Tax Court for additional factual findings.

In October 2011, the IRS issued its audit report on Medtronic, Inc. for fiscal years 2007 and 2008. Medtronic, Inc. reached agreement with the IRS on some, but not all matters related to these fiscal years. The remaining unresolved issue for fiscal years 2007 and 2008 relates to the allocation of income between Medtronic, Inc. and its wholly-owned subsidiary operating in Puerto Rico for the businesses that are the subject of the U.S. Tax Court Case for fiscal years 2005 and 2006.

In April 2014, the IRS issued its audit report on Medtronic, Inc. for fiscal years 2009, 2010, and 2011. Medtronic, Inc. reached agreement with the IRS on some but not all matters related to these fiscal years. The remaining unresolved issue for fiscal years 2009, 2010, and 2011 relates to the allocation of income between Medtronic, Inc. and its wholly-owned subsidiary operating in Puerto Rico for the businesses that are the subject of the U.S. Tax Court Case for fiscal years 2005 and 2006.

In May 2017, the IRS issued its audit report on Medtronic, Inc. for fiscal years 2012, 2013, and 2014. Medtronic, Inc. reached agreement with the IRS on some but not all matters related to these fiscal years. The significant issues that remain unresolved relate to the allocation of income between Medtronic, Inc. and its wholly-owned subsidiary operating in Puerto Rico, and proposed adjustments associated with the utilization of certain net operating losses. The Company disagrees with the IRS and will attempt to resolve these matters at the IRS Appellate level.

Medtronic, Inc.'s fiscal years 2015 and 2016 U.S. federal income tax returns are currently being audited by the IRS.

Covidien and the IRS have concluded and reached agreement on its audit of Covidien's U.S. federal income tax returns for all tax years through 2012. The statute of limitations for Covidien's 2013 and 2014 U.S. federal income tax returns lapsed during the first quarter of fiscal years 2018 and 2019, respectively. Covidien's fiscal year 2015 U.S. federal income tax returns are currently being audited by the IRS.

While it is not possible to predict the outcome for most of the income tax matters discussed above, the Company believes it is possible that charges associated with these matters could have a material adverse impact on the Company's consolidated earnings, financial position, and/or cash flows.

Refer to Note 12 for additional discussion of income taxes.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Guarantees

As a result of the acquisition of Covidien, the Company has a guarantee commitment related to certain contingent tax liabilities as a party to the Tax Sharing Agreement that was entered into on June 29, 2007, between Covidien, Tyco International (now Johnson Controls), and Tyco Electronics (now TE Connectivity), associated with the spin-off from Tyco. The Tax Sharing Agreement covers certain income tax liabilities for periods prior to and including the spin-off. Medtronic's share of the income tax liabilities for these periods is 42 percent, with Johnson Controls and TE Connectivity share being 27 percent, and 31 percent, respectively. If Johnson Controls and TE Connectivity default on their obligations to the Company under the Tax Sharing Agreement, the Company would be liable for the entire amount of these liabilities. All costs and expenses associated with the management of these tax liabilities are being shared equally among the parties. The most significant amounts at risk under this Tax Sharing Agreement were resolved with the U.S. Tax Court and IRS Appeals resolutions reached in May 2016. However, the Tax Sharing Agreement remains in place with respect to income tax liabilities that are not the subject of such resolution, including certain state and international tax matters that remain open.

The Company has used available information to develop its best estimates for certain assets and liabilities related to periods prior to the 2007 separation, including amounts subject to or impacted by the provisions of the Tax Sharing Agreement. The actual amounts that the Company may be required to ultimately accrue or pay under the Tax Sharing Agreement, however, could vary depending upon the outcome of the unresolved tax matters. Final determination of the balances will be made in subsequent periods, primarily related to tax years that remain open for examination. These balances will also be impacted by the filing of final or amended income tax returns in certain jurisdictions where those returns include a combination of Tyco International, Covidien and/or Tyco Electronics legal entities for periods prior to the 2007 separation.

Refer to Note 1 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended April 27, 2018 for additional information.

As part of the Company's sale of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses to Cardinal on July 29, 2017, the Company has indemnified Cardinal for certain contingent tax liabilities related to the divested businesses that existed prior to the date of divestiture. The actual amounts that the Company may be required to ultimately accrue or pay could vary depending upon the outcome of the unresolved tax matters.

In the normal course of business, the Company and/or its affiliates periodically enter into agreements that require one or more of the Company and/or its affiliates to indemnify customers or suppliers for specific risks, such as claims for injury or property damage arising as a result of the Company or its affiliates' products, the negligence of the Company's personnel, or claims alleging that the Company's products infringe on third-party patents or other intellectual property. The Company also offers warranties on various products. The Company's maximum exposure under these guarantees is unable to be estimated. Historically, the Company has not experienced significant losses on these types of guarantees.

The Company believes the ultimate resolution of the above guarantees is not expected to have a material effect on the Company's consolidated earnings, financial position, or cash flows.

18. Segment and Geographic Information

Segment disclosures are on a performance basis consistent with internal management reporting. Net sales of the Company's reportable segments include end-customer revenues from the sale of products the segment develops, manufactures, and distributes. There are certain corporate and centralized expenses that are not allocated to the segments.

The Company's management evaluates performance of the segments and allocates resources based on net sales and segment earnings before interest, taxes, and amortization ("Segment EBITA"). Segment EBITA represents income before income taxes, excluding interest expense, interest income, amortization of intangible assets, centralized distribution

costs, certain corporate charges, and other items not allocated to the segments.

The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies in Note 1 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended April 27, 2018. Certain depreciable assets may be recorded by one segment, while the depreciation expense is allocated to another segment. The allocation of depreciation expense is based on the proportion of the assets used by each segment.

The following tables present reconciliations of financial information from the segments to the applicable line items in the Company's consolidated financial statements:

Net Sales

	Three months ended		Nine months ended	
(in millions)	**January 25, 2019**	**January 26, 2018**	**January 25, 2019**	**January 26, 2018**
Cardiac and Vascular Group	$ 2,786	$ 2,800	$ 8,455	$ 8,219
Minimally Invasive Therapies Group	2,124	2,041	6,223	6,479
Restorative Therapies Group	2,026	1,944	5,968	5,616
Diabetes Group	610	584	1,765	1,495
Total	$ 7,546	$ 7,369	$ 22,411	$ 21,809

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Segment EBITA

	Three months ended		Nine months ended	
(in millions)	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Cardiac and Vascular Group	$ 1,077	$ 1,082	$ 3,268	$ 3,197
Minimally Invasive Therapies Group	828	797	2,397	2,433
Restorative Therapies Group	825	756	2,396	2,186
Diabetes Group	189	187	538	389
Segment EBITA	2,919	2,822	8,599	8,205
Interest expense	(243)	(270)	(726)	(829)
Interest income	55	98	202	290
Amortization of intangible assets	(436)	(461)	(1,327)	(1,375)
Corporate	(323)	(524)	(969)	(1,140)
Centralized distribution costs	(383)	(471)	(1,312)	(1,399)
Restructuring and associated costs	(66)	(30)	(256)	(62)
Acquisition-related items	(17)	(30)	(57)	(101)
Certain litigation charges	(63)	(61)	(166)	(61)
Gain/(loss) on minority investments	7	—	92	—
IPR&D charges	(11)	(46)	(26)	(46)
Exit of businesses	(69)	—	(149)	—
Divestiture-related items	—	—	—	(115)
Gain on sale of businesses	—	—	—	697
Contribution to Medtronic Foundation	—	—	—	(80)
Hurricane Maria	—	—	—	(34)
Income before income taxes	$ 1,370	$ 1,027	$ 3,905	$ 3,950

Geographic Information

Net sales are attributed to the country based on the location of the customer taking possession of the products or in which the services are rendered. The following table presents net sales for the three and nine months ended January 25, 2019 and January 26, 2018 for the Company's country of domicile, countries with significant concentrations, and all other countries:

	Three months ended	Nine months ended

(in millions)	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Ireland	$ 24	$ 20	$ 68	$ 62
United States	4,001	3,912	11,910	11,688
Rest of world	3,521	3,437	10,433	10,059
Total other countries, excluding Ireland	7,522	7,349	22,343	21,747
Total	$ 7,546	$ 7,369	$ 22,411	$ 21,809

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

19. Guarantor Financial Information

Medtronic plc and Medtronic Global Holdings S.C.A. (Medtronic Luxco), a wholly-owned subsidiary guarantor, each have provided full and unconditional guarantees of the obligations of Medtronic, Inc., a wholly-owned subsidiary issuer, under the Senior Notes (Medtronic Senior Notes) and full and unconditional guarantees of the obligations of Covidien International Finance S.A. (CIFSA), a wholly-owned subsidiary issuer, under the Senior Notes (CIFSA Senior Notes). The guarantees of the CIFSA Senior Notes are in addition to the guarantees of the CIFSA Senior Notes by Covidien Ltd. and Covidien Group Holdings Ltd., both of which are wholly-owned subsidiary guarantors of the CIFSA Senior Notes. Additionally, Medtronic plc and Medtronic, Inc. each have provided a full and unconditional guarantee of the obligations of Medtronic Luxco under the Medtronic Luxco Senior Notes. The following is a summary of these guarantees:

Guarantees of Medtronic Senior Notes
- Parent Company Guarantor - Medtronic plc
- Subsidiary Issuer - Medtronic, Inc.
- Subsidiary Guarantor - Medtronic Luxco

Guarantees of Medtronic Luxco Senior Notes
- Parent Company Guarantor - Medtronic plc
- Subsidiary Issuer - Medtronic Luxco
- Subsidiary Guarantor - Medtronic, Inc.

Guarantees of CIFSA Senior Notes
- Parent Company Guarantor - Medtronic plc
- Subsidiary Issuer - CIFSA
- Subsidiary Guarantors - Medtronic Luxco, Covidien Ltd., and Covidien Group Holdings Ltd. (CIFSA Subsidiary Guarantors)

The following presents the Company's consolidating statements of comprehensive income for the three and nine months ended January 25, 2019 and January 26, 2018, condensed consolidating balance sheets at January 25, 2019 and April 27, 2018, and condensed consolidating statements of cash flows for the nine months ended January 25, 2019 and January 26, 2018. The guarantees provided by the parent company guarantor and subsidiary guarantors are joint and several. Condensed consolidating financial information for Medtronic plc, Medtronic Luxco, Medtronic, Inc., CIFSA, and CIFSA Subsidiary Guarantors, on a stand-alone basis, is presented using the equity method of accounting for subsidiaries. Certain reclassifications have been made to prior year financial statements to conform to classifications used in the current year.

During the nine months ended January 25, 2019, the Company undertook certain steps to reorganize ownership of various subsidiaries. The transactions were entirely among subsidiaries under the common control of Medtronic. This reorganization has been reflected as of the beginning of the earliest period presented.

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Consolidating Statement of Comprehensive Income
Three Months Ended January 25, 2019
Medtronic Senior Notes and Medtronic Luxco Senior Notes

(in millions)	Medtronic plc	Medtronic, Inc.	Medtronic Luxco	Subsidiary Non-guarantors	Consolidating Adjustments	Total
Net sales	$ —	$ 281	$ —	$ 7,546	$ (281)	$ 7,546
Costs and expenses:						
Cost of products sold	—	223	—	2,206	(164)	2,265
Research and development expense	—	152	—	409	—	561
Selling, general, and administrative expense	2	362	—	2,232	—	2,596
Amortization of intangible assets	—	2	—	434	—	436
Restructuring charges, net	—	3	—	23	—	26
Certain litigation charges	—	12	—	51	—	63
Other operating expense (income), net	15	(827)	—	987	(118)	57
Operating profit (loss)	(17)	354	—	1,204	1	1,542
Other non-operating (income) expense, net	—	(151)	(200)	(480)	760	(71)
Interest expense	125	501	133	244	(760)	243
Equity in net (income) loss of subsidiaries	(1,410)	(678)	(1,343)	—	3,431	—
Income (loss) before income taxes	1,268	682	1,410	1,440	(3,430)	1,370
Income tax (benefit) provision	(1)	40	—	60	—	99
Net income (loss)	1,269	642	1,410	1,380	(3,430)	1,271
Net (income) loss attributable to noncontrolling interests	—	—	—	(2)	—	(2)
Net income (loss) attributable to Medtronic	1,269	642	1,410	1,378	(3,430)	1,269
Other comprehensive income (loss), net of tax	154	54	154	132	(340)	154
Comprehensive income attributable to noncontrolling interests	—	—	—	(2)	—	(2)
Total comprehensive income (loss)	$ 1,423	$ 696	$ 1,564	$ 1,510	$ (3,770)	$ 1,423

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Consolidating Statement of Comprehensive Income
Nine Months Ended January 25, 2019
Medtronic Senior Notes and Medtronic Luxco Senior Notes

(in millions)	Medtronic plc	Medtronic, Inc.	Medtronic Luxco	Subsidiary Non-guarantors	Consolidating Adjustments	Total
Net sales	$ —	$ 1,007	$ —	$ 22,411	$ (1,007)	$ 22,411
Costs and expenses:						
Cost of products sold	—	776	—	6,538	(642)	6,672
Research and development expense	—	496	—	1,240	—	1,736
Selling, general, and administrative expense	8	1,142	—	6,648	—	7,798
Amortization of intangible assets	—	6	—	1,321	—	1,327
Restructuring charges, net	—	14	—	98	—	112
Certain litigation charges	—	90	—	76	—	166
Other operating expense (income), net	40	(1,759)	—	2,336	(339)	278
Operating profit (loss)	(48)	242	—	4,154	(26)	4,322
Other non-operating (income) expense, net	—	(445)	(539)	(1,411)	2,086	(309)
Interest expense	333	1,444	349	686	(2,086)	726
Equity in net (income) loss of subsidiaries	(3,835)	(2,178)	(3,644)	—	9,657	—
Income (loss) before income taxes	3,454	1,421	3,834	4,879	(9,683)	3,905
Income tax (benefit) provision	(5)	(79)	—	521	—	437
Net income (loss)	3,459	1,500	3,834	4,358	(9,683)	3,468
Net (income) loss attributable to noncontrolling interests	—	—	—	(9)	—	(9)
Net income (loss) attributable to Medtronic	3,459	1,500	3,834	4,349	(9,683)	3,459
Other comprehensive income (loss), net of tax	(719)	(747)	(719)	(779)	2,242	(722)
Comprehensive income attributable to noncontrolling interests	—	—	—	(6)	—	(6)
Total comprehensive income (loss)	$ 2,740	$ 753	$ 3,115	$ 3,573	$ (7,441)	$ 2,740

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Consolidating Statement of Comprehensive Income
Three Months Ended January 26, 2018
Medtronic Senior Notes and Medtronic Luxco Senior Notes

(in millions)	Medtronic plc	Medtronic, Inc.	Medtronic Luxco	Subsidiary Non-guarantors	Consolidating Adjustments	Total
Net sales	$ —	$ 275	$ —	$ 7,369	$ (275)	$ 7,369
Costs and expenses:						
Cost of products sold	—	246	—	2,126	(178)	2,194
Research and development expense	—	166	—	393	—	559
Selling, general, and administrative expense	4	364	—	2,155	—	2,523
Amortization of intangible assets	—	2	—	459	—	461
Restructuring charges, net	—	—	—	7	—	7
Certain litigation charges	—	24	—	37	—	61
Other operating expense (income), net	10	(773)	—	999	(108)	128
Operating profit (loss)	(14)	246	—	1,193	11	1,436
Other non-operating (income) expense, net	—	92	(133)	(355)	535	139
Interest expense	63	464	73	205	(535)	270
Equity in net (income) loss of subsidiaries	1,314	1,350	1,374	—	(4,038)	—
Income (loss) before income taxes	(1,391)	(1,660)	(1,314)	1,343	4,049	1,027
Income tax (benefit) provision	(2)	316	—	2,105	—	2,419
Net income (loss)	(1,389)	(1,976)	(1,314)	(762)	4,049	(1,392)
Net loss attributable to noncontrolling interests	—	—	—	3	—	3
Net income (loss) attributable to Medtronic	(1,389)	(1,976)	(1,314)	(759)	4,049	(1,389)
Other comprehensive (loss) income, net of tax	678	599	678	664	(1,941)	678
Comprehensive loss attributable to noncontrolling interests	—	—	—	3	—	3
Total comprehensive income (loss)	$ (711)	$ (1,377)	$ (636)	$ (95)	$ 2,108	$ (711)

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Consolidating Statement of Comprehensive Income
Nine Months Ended January 26, 2018
Medtronic Senior Notes and Medtronic Luxco Senior Notes

(in millions)	Medtronic plc	Medtronic, Inc.	Medtronic Luxco	Subsidiary Non-guarantors	Consolidating Adjustments	Total
Net sales	$ —	$ 879	$ —	$ 21,807	$ (877)	$ 21,809
Costs and expenses:						
Cost of products sold	—	702	—	6,548	(581)	6,669
Research and development expense	—	495	—	1,169	—	1,664
Selling, general, and administrative expense	9	1,089	—	6,544	—	7,642
Amortization of intangible assets	—	6	—	1,369	—	1,375
Restructuring charges, net	—	2	—	21	—	23
Certain litigation charges	—	24	—	37	—	61
Gain on sale of businesses	—	—	—	(697)	—	(697)
Other operating expense (income), net	35	(1,334)	—	1,981	(322)	360
Operating profit (loss)	(44)	(105)	—	4,835	26	4,712
Other non-operating (income) expense, net	—	(57)	(344)	(1,036)	1,370	(67)
Interest expense	172	1,330	155	542	(1,370)	829
Equity in net (income) loss of subsidiaries	(1,855)	(387)	(1,666)	—	3,908	—
Income (loss) before income taxes	1,639	(991)	1,855	5,329	(3,882)	3,950
Income tax (benefit) provision	(5)	(3)	—	2,328	—	2,320
Net income (loss)	1,644	(988)	1,855	3,001	(3,882)	1,630
Net loss attributable to noncontrolling interests	—	—	—	14	—	14
Net income (loss) attributable to Medtronic	1,644	(988)	1,855	3,015	(3,882)	1,644
Other comprehensive income (loss), net of tax	1,231	1,228	1,231	1,194	(3,653)	1,231
Comprehensive loss attributable to noncontrolling interests	—	—	—	14	—	14
Total comprehensive income (loss)	$ 2,875	$ 240	$ 3,086	$ 4,209	$ (7,535)	$ 2,875

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Condensed Consolidating Balance Sheet
January 25, 2019
Medtronic Senior Notes and Medtronic Luxco Senior Notes

(in millions)	Medtronic plc	Medtronic, Inc.	Medtronic Luxco	Subsidiary Non-guarantors	Consolidating Adjustments	Total
ASSETS						
Current assets:						
Cash and cash equivalents	$ —	$ 16	$ 336	$ 3,351	$ —	$ 3,703
Investments	—	—	—	5,439	—	5,439
Accounts receivable, net	—	—	—	5,854	—	5,854
Inventories, net	—	176	—	3,870	(180)	3,866
Intercompany receivable	46	20,062	—	36,870	(56,978)	—
Other current assets	9	159	3	1,844	—	2,015
Total current assets	55	20,413	339	57,228	(57,158)	20,877
Property, plant, and equipment, net	—	1,439	—	3,154	—	4,593
Goodwill	—	1,883	—	38,120	—	40,003
Other intangible assets, net	—	—	—	20,835	—	20,835
Tax assets	—	447	—	1,049	—	1,496
Investment in subsidiaries	63,260	76,021	64,146	—	(203,427)	—
Intercompany loans receivable	3,000	21	30,022	33,786	(66,829)	—
Other assets	—	255	—	671	—	926
Total assets	$ 66,315	$ 100,479	$ 94,507	$ 154,843	$ (327,414)	$ 88,730
LIABILITIES AND EQUITY						
Current liabilities:						
Current debt obligations	$ —	$ 1	$ 1,000	$ 355	$ —	$ 1,356
Accounts payable	—	459	—	1,247	—	1,706
Intercompany payable	—	20,271	16,601	20,106	(56,978)	—
Accrued compensation	4	733	—	1,059	—	1,796
Accrued income taxes	—	—	—	648	—	648
Other accrued expenses	20	557	32	2,738	—	3,347
Total current liabilities	24	22,021	17,633	26,153	(56,978)	8,853
Long-term debt	—	20,620	845	2,209	—	23,674
Accrued compensation and retirement benefits	—	836	—	477	—	1,313

Accrued income taxes	10	650	—	2,214	—	2,874
Intercompany loans payable	16,452	13,879	19,794	16,704	(66,829)	—
Deferred tax liabilities	—	—	—	1,356	—	1,356
Other liabilities	—	41	—	678	—	719
Total liabilities	16,486	58,047	38,272	49,791	(123,807)	38,789
Shareholders' equity	49,829	42,432	56,235	104,940	(203,607)	49,829
Noncontrolling interests	—	—	—	112	—	112
Total equity	49,829	42,432	56,235	105,052	(203,607)	49,941
Total liabilities and equity	$ 66,315	$ 100,479	$ 94,507	$ 154,843	$ (327,414)	$ 88,730

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Condensed Consolidating Balance Sheet
April 27, 2018
Medtronic Senior Notes and Medtronic Luxco Senior Notes

(in millions)	Medtronic plc	Medtronic, Inc.	Medtronic Luxco	Subsidiary Non-guarantors	Consolidating Adjustments	Total
ASSETS						
Current assets:						
Cash and cash equivalents	$ —	$ 20	$ 1	$ 3,648	$ —	$ 3,669
Investments	—	76	—	7,482	—	7,558
Accounts receivable, net	—	—	—	5,987	—	5,987
Inventories, net	—	165	—	3,539	(125)	3,579
Intercompany receivable	37	23,480	—	33,929	(57,446)	—
Other current assets	6	178	—	2,003	—	2,187
Total current assets	43	23,919	1	56,588	(57,571)	22,980
Property, plant, and equipment, net	—	1,426	—	3,178	—	4,604
Goodwill	—	1,883	—	37,660	—	39,543
Other intangible assets, net	—	12	—	21,711	—	21,723
Tax assets	—	385	—	1,080	—	1,465
Investment in subsidiaries	60,381	73,495	61,461	—	(195,337)	—
Intercompany loans receivable	3,000	6,519	19,337	34,196	(63,052)	—
Other assets	—	223	—	855	—	1,078
Total assets	$ 63,424	$ 107,862	$ 80,799	$ 155,268	$ (315,960)	$ 91,393
LIABILITIES AND EQUITY						
Current liabilities:						
Current debt obligations	$ —	$ —	$ 1,696	$ 362	$ —	$ 2,058
Accounts payable	—	381	—	1,247	—	1,628
Intercompany payable	—	28,401	5,542	23,503	(57,446)	—
Accrued compensation	3	787	—	1,198	—	1,988
Accrued income taxes	—	—	—	979	—	979
Other accrued expenses	16	359	4	3,052	—	3,431
Total current liabilities	19	29,928	7,242	30,341	(57,446)	10,084
Long-term debt	—	20,598	844	2,257	—	23,699
Accrued compensation and retirement benefits	—	902	—	523	—	1,425

Accrued income taxes	10	531	—	2,510	—	3,051
Intercompany loans payable	12,675	14,339	19,335	16,703	(63,052)	—
Deferred tax liabilities	—	—	—	1,423	—	1,423
Other liabilities	—	68	—	821	—	889
Total liabilities	12,704	66,366	27,421	54,578	(120,498)	40,571
Shareholders' equity	50,720	41,496	53,378	100,588	(195,462)	50,720
Noncontrolling interests	—	—	—	102	—	102
Total equity	50,720	41,496	53,378	100,690	(195,462)	50,822
Total liabilities and equity	$ 63,424	$ 107,862	$ 80,799	$ 155,268	$ (315,960)	$ 91,393

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Condensed Consolidating Statement of Cash Flows
Nine Months Ended January 25, 2019
Medtronic Senior Notes and Medtronic Luxco Senior Notes

(in millions)	Medtronic plc	Medtronic, Inc.	Medtronic Luxco	Subsidiary Non-guarantors	Consolidating Adjustments	Total
Operating Activities:						
Net cash provided by (used in) operating activities	$ 100	$ (619)	$ 200	$ 5,239	$ —	$ 4,920
Investing Activities:						
Acquisitions, net of cash acquired	—	—	—	(1,615)	—	(1,615)
Additions to property, plant, and equipment	—	(207)	—	(592)	—	(799)
Purchases of investments	—	—	—	(1,987)	—	(1,987)
Sales and maturities of investments	—	76	—	4,083	—	4,159
Capital contribution paid	(18)	(47)	—	—	65	—
Other investing activities	—	—	—	(3)	—	(3)
Net cash provided by (used in) investing activities	(18)	(178)	—	(114)	65	(245)
Financing Activities:						
Change in current debt obligations, net	—	—	(696)	—	—	(696)
Issuance of long-term debt	—	—	—	3	—	3
Payments on long-term debt	—	—	—	(29)	—	(29)
Dividends to shareholders	(2,022)	—	—	—	—	(2,022)
Issuance of ordinary shares	891	—	—	—	—	891
Repurchase of ordinary shares	(2,728)	—	—	—	—	(2,728)
Net intercompany loan borrowings (repayments)	3,777	793	814	(5,384)	—	—
Capital contribution received	—	—	—	65	(65)	—
Other financing activities	—	—	17	(7)	—	10
Net cash provided by (used in) financing activities	(82)	793	135	(5,352)	(65)	(4,571)
Effect of exchange rate changes on cash and cash equivalents	—	—	—	(70)	—	(70)
Net change in cash and cash equivalents	—	(4)	335	(297)	—	34
Cash and cash equivalents at beginning of period	—	20	1	3,648	—	3,669
Cash and cash equivalents at end of period	$ —	$ 16	$ 336	$ 3,351	$ —	$ 3,703

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Condensed Consolidating Statement of Cash Flows
Nine Months Ended January 26, 2018
Medtronic Senior Notes and Medtronic Luxco Senior Notes

(in millions)	Medtronic plc	Medtronic, Inc.	Medtronic Luxco	Subsidiary Non-guarantors	Consolidating Adjustments	Total
Operating Activities:						
Net cash provided by (used in) operating activities	$ 172	$ (958)	$ 200	$ 4,232	$ —	$ 3,646
Investing Activities:						
Acquisitions, net of cash acquired	—	—	—	(111)	—	(111)
Proceeds from sale of businesses	—	—	—	6,058	—	6,058
Additions to property, plant, and equipment	—	(234)	—	(542)	—	(776)
Purchases of investments	—	—	—	(2,479)	—	(2,479)
Sales and maturities of investments	—	—	—	3,060	—	3,060
Capital contribution paid	—	(59)	(4,200)	—	4,259	—
Other investing activities	—	—	—	(5)	—	(5)
Net cash provided by (used in) investing activities	—	(293)	(4,200)	5,981	4,259	5,747
Financing Activities:						
Change in current debt obligations, net	—	—	(397)	6	—	(391)
Issuance of long-term debt	—	—	—	21	—	21
Payments on long-term debt	—	(3,000)	—	(1,167)	—	(4,167)
Dividends to shareholders	(1,870)	—	—	—	—	(1,870)
Issuance of ordinary shares	333	—	—	—	—	333
Repurchase of ordinary shares	(1,964)	—	—	—	—	(1,964)
Net intercompany loan borrowings (repayments)	3,329	4,244	4,453	(12,026)	—	—
Capital contribution received	—	—	—	4,259	(4,259)	—
Other financing activities	—	—	—	(88)	—	(88)
Net cash provided by (used in) financing activities	(172)	1,244	4,056	(8,995)	(4,259)	(8,126)
Effect of exchange rate changes on cash and cash equivalents	—	—	—	124	—	124
Net change in cash and cash equivalents	—	(7)	56	1,342	—	1,391
Cash and cash equivalents at beginning of period	—	45	5	4,917	—	4,967
Cash and cash equivalents at end of period	$ —	$ 38	$ 61	$ 6,259	$ —	$ 6,358

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Consolidating Statement of Comprehensive Income
Three Months Ended January 25, 2019
CIFSA Senior Notes

(in millions)	Medtronic plc	CIFSA	CIFSA Subsidiary Guarantors	Subsidiary Non-guarantors	Consolidating Adjustments	Total
Net sales	$ —	$ —	$ —	$ 7,546	$ —	$ 7,546
Costs and expenses:						
Cost of products sold	—	—	—	2,265	—	2,265
Research and development expense	—	—	—	561	—	561
Selling, general, and administrative expense	2	—	1	2,593	—	2,596
Amortization of intangible assets	—	—	—	436	—	436
Restructuring charges, net	—	—	—	26	—	26
Certain litigation charges	—	—	—	63	—	63
Other operating expense, net	15	—	—	42	—	57
Operating profit (loss)	(17)	—	(1)	1,560	—	1,542
Other non-operating (income) expense, net	—	(9)	(207)	(190)	335	(71)
Interest expense	125	23	132	298	(335)	243
Equity in net (income) loss of subsidiaries	(1,410)	(655)	(1,336)	—	3,401	—
Income (loss) before income taxes	1,268	641	1,410	1,452	(3,401)	1,370
Income tax (benefit) provision	(1)	—	—	100	—	99
Net income (loss)	1,269	641	1,410	1,352	(3,401)	1,271
Net loss attributable to noncontrolling interests	—	—	—	(2)	—	(2)
Net income (loss) attributable to Medtronic	1,269	641	1,410	1,350	(3,401)	1,269
Other comprehensive income (loss), net of tax	154	95	154	154	(403)	154
Comprehensive income attributable to noncontrolling interests	—	—	—	(2)	—	(2)
Total comprehensive income (loss)	$ 1,423	$ 736	$ 1,564	$ 1,504	$ (3,804)	$ 1,423

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Consolidating Statement of Comprehensive Income
Nine Months Ended January 25, 2019
CIFSA Senior Notes

(in millions)	Medtronic plc	CIFSA	CIFSA Subsidiary Guarantors	Subsidiary Non-guarantors	Consolidating Adjustments	Total
Net sales	$ —	$ —	$ —	$ 22,411	$ —	$ 22,411
Costs and expenses:						
Cost of products sold	—	—	—	6,672	—	6,672
Research and development expense	—	—	—	1,736	—	1,736
Selling, general, and administrative expense	8	1	2	7,787	—	7,798
Amortization of intangible assets	—	—	—	1,327	—	1,327
Restructuring charges, net	—	—	—	112	—	112
Certain litigation charges	—	—	—	166	—	166
Other operating expense, net	40	—	—	238	—	278
Operating profit (loss)	(48)	(1)	(2)	4,373	—	4,322
Other non-operating (income) expense, net	—	(29)	(559)	(614)	893	(309)
Interest expense	333	66	348	872	(893)	726
Equity in net (income) loss of subsidiaries	(3,835)	(2,271)	(3,626)	—	9,732	—
Income (loss) before income taxes	3,454	2,233	3,835	4,115	(9,732)	3,905
Income tax (benefit) provision	(5)	—	—	442	—	437
Net income (loss)	3,459	2,233	3,835	3,673	(9,732)	3,468
Net loss attributable to noncontrolling interests	—	—	—	(9)	—	(9)
Net income (loss) attributable to Medtronic	3,459	2,233	3,835	3,664	(9,732)	3,459
Other comprehensive income (loss), net of tax	(719)	69	(719)	(722)	1,369	(722)
Comprehensive income attributable to noncontrolling interests	—	—	—	(6)	—	(6)
Total comprehensive income (loss)	$ 2,740	$ 2,302	$ 3,116	$ 2,945	$ (8,363)	$ 2,740

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Consolidating Statement of Comprehensive Income
Three Months Ended January 26, 2018
CIFSA Senior Notes

(in millions)	Medtronic plc	CIFSA	CIFSA Subsidiary Guarantors	Subsidiary Non-guarantors	Consolidating Adjustments	Total
Net sales	$ —	$ —	$ —	$ 7,369	$ —	$ 7,369
Costs and expenses:						
Cost of products sold	—	—	—	2,194	—	2,194
Research and development expense	—	—	—	559	—	559
Selling, general, and administrative expense	4	—	—	2,519	—	2,523
Amortization of intangible assets	—	—	—	461	—	461
Restructuring charges, net	—	—	—	7	—	7
Certain litigation charges	—	—	—	61	—	61
Gain on sale of businesses	—	—	—	—	—	—
Other operating expense, net	10	—	—	118	—	128
Operating profit (loss)	(14)	—	—	1,450	—	1,436
Other non-operating (income) expense, net	—	(13)	(137)	83	206	139
Interest expense	63	19	73	321	(206)	270
Equity in net (income) loss of subsidiaries	1,314	(921)	1,378	—	(1,771)	—
Income (loss) before income taxes	(1,391)	915	(1,314)	1,046	1,771	1,027
Income tax (benefit) provision	(2)	—	—	2,421	—	2,419
Net income (loss)	(1,389)	915	(1,314)	(1,375)	1,771	(1,392)
Net loss attributable to noncontrolling interests	—	—	—	3	—	3
Net income (loss) attributable to Medtronic	(1,389)	915	(1,314)	(1,372)	1,771	(1,389)
Other comprehensive (loss) income, net of tax	678	52	678	678	(1,408)	678
Comprehensive loss attributable to noncontrolling interests	—	—	—	3	—	3
Total comprehensive income (loss)	$ (711)	$ 967	$ (636)	$ (694)	$ 363	$ (711)

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Consolidating Statement of Comprehensive Income
Nine Months Ended January 26, 2018
CIFSA Senior Notes

(in millions)	Medtronic plc	CIFSA	CIFSA Subsidiary Guarantors	Subsidiary Non-guarantors	Consolidating Adjustments	Total
Net sales	$ —	$ —	$ —	$ 21,809	$ —	$ 21,809
Costs and expenses:						
Cost of products sold	—	—	—	6,669	—	6,669
Research and development expense	—	—	—	1,664	—	1,664
Selling, general, and administrative expense	9	—	1	7,632	—	7,642
Amortization of intangible assets	—	—	—	1,375	—	1,375
Restructuring charges, net	—	—	—	23	—	23
Certain litigation charges	—	—	—	61	—	61
Gain on sale of businesses	—	—	—	(697)	—	(697)
Other operating expense, net	35	1	—	324	—	360
Operating profit (loss)	(44)	(1)	(1)	4,758	—	4,712
Other non-operating (income) expense, net	—	(45)	(355)	(169)	502	(67)
Interest expense	172	63	156	940	(502)	829
Equity in net (income) loss of subsidiaries	(1,855)	(3,062)	(1,657)	—	6,574	—
Income (loss) before income taxes	1,639	3,043	1,855	3,987	(6,574)	3,950
Income tax (benefit) provision	(5)	—	—	2,325	—	2,320
Net income (loss)	1,644	3,043	1,855	1,662	(6,574)	1,630
Net loss attributable to noncontrolling interests	—	—	—	14	—	14
Net income (loss) attributable to Medtronic	1,644	3,043	1,855	1,676	(6,574)	1,644
Other comprehensive income (loss), net of tax	1,231	(7)	1,231	1,231	(2,455)	1,231
Comprehensive loss attributable to non-controlling interests	—	—	—	14	—	14
Total comprehensive income (loss)	$ 2,875	$ 3,036	$ 3,086	$ 2,907	$ (9,029)	$ 2,875

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Condensed Consolidating Balance Sheet
January 25, 2019
CIFSA Senior Notes

(in millions)	Medtronic plc	CIFSA	CIFSA Subsidiary Guarantors	Subsidiary Non-guarantors	Consolidating Adjustments	Total
ASSETS						
Current assets:						
Cash and cash equivalents	$ —	$ —	$ 336	$ 3,367	$ —	$ 3,703
Investments	—	—	—	5,439	—	5,439
Accounts receivable, net	—	—	—	5,854	—	5,854
Inventories, net	—	—	—	3,866	—	3,866
Intercompany receivable	46	—	1,362	16,616	(18,024)	—
Other current assets	9	—	3	2,003	—	2,015
Total current assets	55	—	1,701	37,145	(18,024)	20,877
Property, plant, and equipment, net	—	—	—	4,593	—	4,593
Goodwill	—	—	—	40,003	—	40,003
Other intangible assets, net	—	—	—	20,835	—	20,835
Tax assets	—	—	—	1,496	—	1,496
Investment in subsidiaries	63,260	33,203	62,790	—	(159,253)	—
Intercompany loans receivable	3,000	1,061	30,022	19,894	(53,977)	—
Other assets	—	—	—	926	—	926
Total assets	$ 66,315	$ 34,264	$ 94,513	$ 124,892	$ (231,254)	$ 88,730
LIABILITIES AND EQUITY						
Current liabilities:						
Current debt obligations	$ —	$ —	$ 1,000	$ 356	$ —	$ 1,356
Accounts payable	—	—	—	1,706	—	1,706
Intercompany payable	—	1,302	16,601	121	(18,024)	—
Accrued compensation	4	—	—	1,792	—	1,796
Accrued income taxes	—	—	—	648	—	648
Other accrued expenses	20	12	37	3,278	—	3,347
Total current liabilities	24	1,314	17,638	7,901	(18,024)	8,853
Long-term debt	—	2,095	845	20,734	—	23,674
Accrued compensation and retirement benefits	—	—	—	1,313	—	1,313

Accrued income taxes	10	—	—	2,864	—	2,874
Intercompany loans payable	16,452	100	19,794	17,631	(53,977)	—
Deferred tax liabilities	—	—	—	1,356	—	1,356
Other liabilities	—	—	1	718	—	719
Total liabilities	16,486	3,509	38,278	52,517	(72,001)	38,789
Shareholders' equity	49,829	30,755	56,235	72,263	(159,253)	49,829
Noncontrolling interests	—	—	—	112	—	112
Total equity	49,829	30,755	56,235	72,375	(159,253)	49,941
Total liabilities and equity	$ 66,315	$ 34,264	$ 94,513	$ 124,892	$ (231,254)	$ 88,730

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Condensed Consolidating Balance Sheet
April 27, 2018
CIFSA Senior Notes

(in millions)	Medtronic plc	CIFSA	CIFSA Subsidiary Guarantors	Subsidiary Non-guarantors	Consolidating Adjustments	Total
ASSETS						
Current assets:						
Cash and cash equivalents	$ —	$ —	$ 1	$ 3,668	$ —	$ 3,669
Investments	—	—	—	7,558	—	7,558
Accounts receivable, net	—	—	—	5,987	—	5,987
Inventories, net	—	—	—	3,579	—	3,579
Intercompany receivable	37	—	1,343	5,560	(6,940)	—
Other current assets	6	—	—	2,181	—	2,187
Total current assets	43	—	1,344	28,533	(6,940)	22,980
Property, plant, and equipment, net	—	—	—	4,604	—	4,604
Goodwill	—	—	—	39,543	—	39,543
Other intangible assets, net	—	—	—	21,723	—	21,723
Tax assets	—	—	—	1,465	—	1,465
Investment in subsidiaries	60,381	31,239	60,122	—	(151,742)	—
Intercompany loans receivable	3,000	1,291	19,337	19,436	(43,064)	—
Other assets	—	—	—	1,078	—	1,078
Total assets	$ 63,424	$ 32,530	$ 80,803	$ 116,382	$ (201,746)	$ 91,393
LIABILITIES AND EQUITY						
Current liabilities:						
Current debt obligations	$ —	$ —	$ 1,696	$ 362	$ —	$ 2,058
Accounts payable	—	—	—	1,628	—	1,628
Intercompany payable	—	1,283	5,542	115	(6,940)	—
Accrued compensation	3	—	—	1,985	—	1,988
Accrued income taxes	—	—	—	979	—	979
Other accrued expenses	16	21	8	3,386	—	3,431
Total current liabilities	19	1,304	7,246	8,455	(6,940)	10,084
Long-term debt	—	2,111	844	20,744	—	23,699
Accrued compensation and retirement benefits	—	—	—	1,425	—	1,425

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Accrued income taxes	10	—	—	3,041	—	3,051
Intercompany loans payable	12,675	100	19,335	10,954	(43,064)	—
Deferred tax liabilities	—	—	—	1,423	—	1,423
Other liabilities	—	—	—	889	—	889
Total liabilities	12,704	3,515	27,425	46,931	(50,004)	40,571
Shareholders' equity	50,720	29,015	53,378	69,349	(151,742)	50,720
Noncontrolling interests	—	—	—	102	—	102
Total Equity	50,720	29,015	53,378	69,451	(151,742)	50,822
Total liabilities and equity	$ 63,424	$ 32,530	$ 80,803	$ 116,382	$ (201,746)	$ 91,393

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Condensed Consolidating Statement of Cash Flows
Nine Months Ended January 25, 2019
CIFSA Senior Notes

(in millions)	Medtronic plc	CIFSA	CIFSA Subsidiary Guarantors	Subsidiary Non-guarantors	Consolidating Adjustments	Total
Operating Activities:						
Net cash provided by (used in) operating activities	$ 100	$ (62)	$ 219	$ 4,663	$ —	$ 4,920
Investing Activities:						
Acquisitions, net of cash acquired	—	—	—	(1,615)	—	(1,615)
Additions to property, plant, and equipment	—	—	—	(799)	—	(799)
Purchases of investments	—	—	—	(1,987)	—	(1,987)
Sales and maturities of investments	—	—	—	4,159	—	4,159
Capital contribution paid	(18)	(187)	—	—	205	—
Other investing activities	—	—	—	(3)	—	(3)
Net cash provided by (used in) investing activities	(18)	(187)	—	(245)	205	(245)
Financing Activities:						
Change in current debt obligations, net	—	—	(696)	—	—	(696)
Issuance of long-term debt	—	—	—	3	—	3
Payments on long-term debt	—	—	—	(29)	—	(29)
Dividends to shareholders	(2,022)	—	—	—	—	(2,022)
Issuance of ordinary shares	891	—	—	—	—	891
Repurchase of ordinary shares	(2,728)	—	—	—	—	(2,728)
Net intercompany loan borrowings (repayments)	3,777	249	795	(4,821)	—	—
Capital contribution received	—	—	—	205	(205)	—
Other financing activities	—	—	17	(7)	—	10
Net cash provided by (used in) financing activities	(82)	249	116	(4,649)	(205)	(4,571)
Effect of exchange rate changes on cash and cash equivalents	—	—	—	(70)	—	(70)
Net change in cash and cash equivalents	—	—	335	(301)	—	34
Cash and cash equivalents at beginning of period	—	—	1	3,668	—	3,669
Cash and cash equivalents at end of period	$ —	$ —	$ 336	$ 3,367	$ —	$ 3,703

Medtronic plc
Notes to Consolidated Financial Statements
(Unaudited)

Condensed Consolidating Statement of Cash Flows
Nine Months Ended January 26, 2018
CIFSA Senior Notes

(in millions)	Medtronic plc	CIFSA	CIFSA Subsidiary Guarantors	Subsidiary Non-guarantors	Consolidating Adjustments	Total
Operating Activities:						
Net cash provided by (used in) operating activities	$ 172	$ 978	$ 210	$ 3,334	$ (1,048)	$ 3,646
Investing Activities:						
Acquisitions, net of cash acquired	—	—	—	(111)	—	(111)
Proceeds from sale of businesses	—	—	—	6,058	—	6,058
Additions to property, plant, and equipment	—	—	—	(776)	—	(776)
Purchases of investments	—	—	—	(2,479)	—	(2,479)
Sales and maturities of investments	—	—	—	3,060	—	3,060
Capital contributions paid	—	(531)	(4,200)	—	4,731	—
Other investing activities	—	—	—	(5)	—	(5)
Net cash provided by (used in) investing activities	—	(531)	(4,200)	5,747	4,731	5,747
Financing Activities:						
Change in current debt obligations, net	—	—	(397)	6	—	(391)
Issuance of long-term debt	—	—	—	21	—	21
Payments on long-term debt	—	(1,150)	—	(3,017)	—	(4,167)
Dividends to shareholders	(1,870)	—	—	—	—	(1,870)
Issuance of ordinary shares	333	—	—	—	—	333
Repurchase of ordinary shares	(1,964)	—	—	—	—	(1,964)
Net intercompany loan borrowings (repayments)	3,329	670	4,443	(8,442)	—	—
Intercompany dividend paid	—	—	—	(1,048)	1,048	—
Capital contributions received	—	—	—	4,731	(4,731)	—
Other financing activities	—	—	—	(88)	—	(88)
Net cash provided by (used in) financing activities	(172)	(480)	4,046	(7,837)	(3,683)	(8,126)
Effect of exchange rate changes on cash and cash equivalents	—	—	—	124	—	124
Net change in cash and cash equivalents	—	(33)	56	1,368	—	1,391
Cash and cash equivalents at beginning of period	—	33	5	4,929	—	4,967
Cash and cash equivalents at end of period	$ —	$ —	$ 61	$ 6,297	$ —	$ 6,358

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

UNDERSTANDING OUR FINANCIAL INFORMATION

The following discussion and analysis provides information management believes to be relevant to understanding the financial condition and results of operations of Medtronic plc and its subsidiaries (Medtronic plc, Medtronic, or the Company, or we, us, or our). For a full understanding of financial condition and results of operations, you should read this discussion along with management's discussion and analysis of financial condition and results of operations in our Annual Report on Form 10-K for the fiscal year ended April 27, 2018. In addition, you should read this discussion along with our consolidated financial statements and related notes thereto at and for the three and nine months ended January 25, 2019.

Financial Trends

Throughout this Management's Discussion and Analysis, we present certain financial measures that we use to evaluate the operational performance of the Company and as a basis for strategic planning; however, such financial measures are not presented in our financial statements prepared in accordance with generally accepted accounting principles in the United States (U.S.) (U.S. GAAP). These financial measures are considered "non-GAAP financial measures" and are intended to supplement, and should not be considered as superior to, financial measures presented in accordance with U.S. GAAP. We generally use non-GAAP financial measures to facilitate management's review of the operational performance of the Company and as a basis for strategic planning. We believe that non-GAAP financial measures provide information useful to investors in understanding the Company's underlying operational performance and trends and may facilitate comparisons with the performance of other companies in the medical technologies industry.

As presented in the GAAP to Non-GAAP Reconciliations section below, our non-GAAP financial measures exclude the impact of certain charges or gains that contribute to or reduce earnings and that may affect financial trends, and include certain charges or benefits that result from transactions or events that we believe may or may not recur with similar materiality or impact to our operations in future periods (Non-GAAP Adjustments).

In the event there is a Non-GAAP Adjustment recognized in our operating results, the tax cost or benefit attributable to that item is separately calculated and reported. Because the effective rate can be significantly impacted by the Non-GAAP Adjustments that take place during the period, we often refer to our tax rate using both the effective rate and the non-GAAP nominal tax rate (Non-GAAP Nominal Tax Rate). The Non-GAAP Nominal Tax Rate is calculated as the income tax provision, adjusted for the impact of Non-GAAP Adjustments, as a percentage of income before income taxes, excluding Non-GAAP Adjustments.

Free cash flow is a non-GAAP financial measure calculated by subtracting property, plant, and equipment additions from operating cash flows.

Refer to the "GAAP to Non-GAAP Reconciliations," "Income Taxes," and "Free Cash Flow" sections for reconciliations of the non-GAAP financial measures to their most directly comparable financial measures prepared in accordance with U.S. GAAP.

EXECUTIVE LEVEL OVERVIEW

Medtronic is among the world's largest medical technology, services, and solutions companies - alleviating pain, restoring health, and extending life for millions of people around the world. Our primary products include those for cardiac rhythm disorders, cardiovascular disease, advanced and general surgical care, respiratory and monitoring solutions, renal care, neurological disorders, spinal conditions and musculoskeletal trauma, urological and digestive disorders, and ear, nose, and throat, and diabetes conditions.

The table below presents net income attributable to Medtronic and our diluted earnings per share for the three and nine months ended January 25, 2019 and January 26, 2018:

	Three months ended			Nine months ended		
(in millions, except per share data)	**January 25, 2019**	**January 26, 2018**	**% Change**	**January 25, 2019**	**January 26, 2018**	**% Change**

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Net income (loss) attributable to Medtronic	$ 1,269	$ (1,389)	191%	$ 3,459	$ 1,644	110%
Diluted earnings (loss) per share	$ 0.94	$ (1.03)	191%	$ 2.54	$ 1.20	112%

The increase in net income attributable to Medtronic and diluted earnings per share (EPS) for the three and nine months ended January 25, 2019 as compared to the corresponding periods in the prior fiscal year, was primarily attributable to the tax charge recognized during the three and nine months ended January 26, 2018 related to the enactment of U.S. comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). Further contributing to the increase in net income and diluted EPS for the three and nine months ended January 25, 2019 were decreases in our other operating expense, net, other non-operating (income) expense, net, and interest expense. For the nine months ended January 25, 2019, the increase in net income and diluted EPS was partially offset by the $697 million gain on the sale of our Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses within the Minimally Invasive Therapies Group on July 29, 2017 and increases in research and development expense and certain litigation charges. Refer to the "Costs and Expenses" section of this Management's Discussion and Analysis for more information on the items impacting net income attributable to Medtronic and diluted EPS during the three and nine months ended January 25, 2019 and January 26, 2018.

GAAP to Non-GAAP Reconciliations The tables below present our GAAP to Non-GAAP reconciliations for the three and nine months ended January 25, 2019 and January 26, 2018:

(in millions, except per share data)	Three months ended January 25, 2019				
	Income Before Income Taxes	Income Tax Provision (Benefit)	Net Income Attributable to Medtronic	Diluted EPS[1]	Effective Tax Rate
GAAP	$ 1,370	$ 99	$ 1,269	$ 0.94	7.2 %
Non-GAAP Adjustments:					
Restructuring and associated costs [2]	66	12	54	0.04	18.2
Acquisition-related items [3]	17	5	12	0.01	29.4
Certain litigation charges	63	12	51	0.04	19.0
(Gain)/loss on minority investments [4]	(7)	(1)	(6)	—	14.3
IPR&D charges [5]	11	3	8	0.01	27.3
Exit of businesses [6]	69	13	56	0.04	18.8
Amortization of intangible assets	436	65	371	0.27	14.9
Certain tax adjustments, net [7]	—	64	(64)	(0.05)	—
Non-GAAP	$ 2,025	$ 272	$ 1,751	$ 1.29	13.4 %

(in millions, except per share data)	Three months ended January 26, 2018				
	Income Before Income Taxes	Income Tax Provision (Benefit)	Net (Loss) Income Attributable to Medtronic	Diluted (LPS) EPS[1] [8]	Effective Tax Rate
GAAP	$ 1,027	$ 2,419	$ (1,389)	$ (1.03)	235.5 %
Non-GAAP Adjustments:					
Restructuring and associated costs [2]	30	4	26	0.02	13.3
Acquisition-related items [9]	30	13	17	0.01	43.3
Certain litigation charges	61	8	53	0.04	13.1
Investment loss [10]	227	(1)	228	0.17	(0.4)
IPR&D charges [5]	46	5	41	0.03	10.9
Amortization of intangible assets	461	87	374	0.27	18.9
Certain tax adjustments, net [11]	—	(2,242)	2,242	1.64	—
Non-GAAP	$ 1,882	$ 293	$ 1,592	$ 1.17	15.6 %

(1) Amounts in this column have been intentionally rounded to the nearest $0.01 and, therefore, may not sum.
(2) Associated costs include costs incurred as a direct result of the restructuring program, such as salaries for employees supporting the program and consulting expenses.
(3) The charges include unvested stock option payouts and investment banker and other transaction fees, along with integration-related costs incurred in connection with the Covidien acquisition and changes in the fair value of contingent consideration.

(4) Unrealized and realized gains and losses on our minority investments.
(5) The charges were recognized in connection with the impairment of in-process research and development ("IPR&D") assets.
(6) The net charge relates to business exits and is primarily comprised of intangible asset impairments.
(7) The net benefit relates to the impact of U.S. tax reform, intercompany legal entity restructuring, and the finalization of certain income tax aspects of the divestiture of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses within the Minimally Invasive Therapies Group on July 29, 2017.
(8) GAAP diluted LPS for the three months ended January 26, 2018 is calculated using diluted weighted average shares outstanding of 1,354.0 million, which is the same as basic weighted average shares, due to the net loss resulting from the tax charge as discussed in footnote (11) below. Non-GAAP diluted EPS for the respective period is calculated using diluted weighted average shares of 1,364.5 million as the Company had non-GAAP net income for the period.
(9) The charges primarily include integration-related costs incurred in connection with the Covidien acquisition and changes in the fair value of contingent consideration.
(10) The charge was recognized in connection with the impairment of certain cost and equity method investments.
(11) The net charge primarily relates to the impact from U.S. tax reform, inclusive of the transition tax, remeasurement of deferred tax assets and liabilities, and the decrease in the U.S. statutory tax rate.

Non-GAAP diluted EPS for the three months ended January 25, 2019 was favorably impacted by an increase in net sales and decreases in other operating expense, net and interest expense when compared to the corresponding period in the prior fiscal year. These decreases were partially offset by an increase in cost of products sold and a decrease in other non-operating (income) expense, net.

	Nine months ended January 25, 2019				
(in millions, except per share data)	Income Before Income Taxes	Income Tax Provision (Benefit)	Net Income Attributable to Medtronic	Diluted EPS[1]	Effective Tax Rate
GAAP	$ 3,905	$ 437	$ 3,459	$ 2.54	11.2 %
Non-GAAP Adjustments:					
Restructuring and associated costs [2]	256	40	216	0.16	15.6
Acquisition-related items [3]	57	13	44	0.03	22.8
Certain litigation charges	166	24	142	0.10	14.5
(Gain)/loss on minority investments [4]	(92)	(9)	(83)	(0.06)	9.8
IPR&D charges [5]	26	3	23	0.02	11.5
Exit of businesses [6]	149	31	118	0.09	20.8
Amortization of intangible assets	1,327	199	1,128	0.83	15.0
Certain tax adjustments, net [7]	—	35	(35)	(0.03)	—
Non-GAAP	$ 5,794	$ 773	$ 5,012	$ 3.69	13.3 %

	Nine months ended January 26, 2018				
(in millions, except per share data)	Income Before Income Taxes	Income Tax Provision (Benefit)	Net Income Attributable to Medtronic	Diluted EPS[1]	Effective Tax Rate
GAAP	$ 3,950	$ 2,320	$ 1,644	$ 1.20	58.7 %
Non-GAAP Adjustments:					
Restructuring and associated costs [2]	62	10	52	0.04	16.1
Acquisition-related items [8]	101	35	66	0.05	34.7
Divestiture-related items [9]	115	12	103	0.08	10.4
Certain litigation charges	61	8	53	0.04	13.1
Investment loss [10]	227	(1)	228	0.17	(0.4)
IPR&D charges [11]	46	5	41	0.03	10.9
Gain on sale of businesses [12]	(697)	—	(697)	(0.51)	—
Hurricane Maria [13]	34	1	33	0.02	2.9
Contribution to Medtronic Foundation	80	26	54	0.04	32.5
Amortization of intangible assets	1,375	241	1,134	0.83	17.5
Certain tax adjustments, net [14]	—	(1,877)	1,877	1.37	—

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

Non-GAAP	$ 5,354	$ 780	$ 4,588	$ 3.35	14.6 %

(1) Amounts in this column have been intentionally rounded to the nearest $0.01 and, therefore, may not sum.
(2) Associated costs include costs incurred as a direct result of the restructuring program, such as salaries for employees supporting the program and consulting expenses.
(3) The charges include unvested stock option payouts and investment banker and other transaction fees, along with integration-related costs incurred in connection with the Covidien acquisition and changes in the fair value of contingent consideration.
(4) Unrealized and realized gains and losses on our minority investments.
(5) The charges represent acquired IPR&D in connection with an asset acquisition and charges recognized in connection with the impairment of IPR&D assets.
(6) The net charge relates to business exits and is primarily comprised of intangible asset impairments.
(7) The net benefit relates to the impact of U.S. tax reform, intercompany legal entity restructuring, and the finalization of certain income tax aspects of the divestiture of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses within the Minimally Invasive Therapies Group on July 29, 2017.
(8) The charges primarily include integration-related costs incurred in connection with the Covidien acquisition and changes in the fair value of contingent consideration.

(9) The transaction expenses incurred in connection with the divestiture of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses.
(10) The charge was recognized in connection with the impairment of certain cost and equity method investments.
(11) The charge was recognized in connection with the impairment of IPR&D assets.
(12) The gain on the divestiture of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses.
(13) The charges represent idle facility costs, asset write-downs, and humanitarian efforts related to Hurricane Maria.
(14) The net charge primarily relates to the impact of U.S. tax reform, inclusive of the transition tax, remeasurement of deferred tax assets and liabilities, and the decrease in the U.S. statutory tax rate. Additionally, the net charge includes the impacts from the divestiture of our Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses, partially offset by the tax effects from the intercompany sale of intellectual property.

Non-GAAP diluted EPS for the nine months ended January 25, 2019 was favorably impacted by an increase in net sales, along with decreases in other operating expense, net and interest expense when compared to the corresponding period in the prior fiscal year, partially offset by increases in selling, general, and administrative expense and research development expense, along with a decrease in other non-operating (income) expense, net.

NET SALES

Segment and Division

The table below illustrates net sales by segment and division for the three and nine months ended January 25, 2019 and January 26, 2018:

	Three months ended			Nine months ended		
(in millions)	January 25, 2019	January 26, 2018	% Change	January 25, 2019	January 26, 2018	% Change
Cardiac Rhythm & Heart Failure	$ 1,397	$ 1,457	(4)%	$ 4,295	$ 4,314	— %
Coronary & Structural Heart	913	886	3	2,736	2,557	7
Aortic, Peripheral & Venous	476	457	4	1,424	1,348	6
Cardiac and Vascular Group	2,786	2,800	(1)	8,455	8,219	3
Surgical Innovations	1,434	1,384	4	4,224	4,024	5
Respiratory, Gastrointestinal, & Renal	690	657	5	1,999	2,455	(19)
Minimally Invasive Therapies Group	2,124	2,041	4	6,223	6,479	(4)
Spine	655	661	(1)	1,963	1,969	—
Brain Therapies	650	585	11	1,867	1,682	11
Specialty Therapies	407	398	2	1,196	1,132	6
Pain Therapies	314	300	5	942	833	13
Restorative Therapies Group	2,026	1,944	4	5,968	5,616	6
Diabetes Group	610	584	4	1,765	1,495	18
Total	$ 7,546	$ 7,369	2 %	$ 22,411	$ 21,809	3 %

Our performance displays our continued execution against our three growth strategies: therapy innovation, globalization, and economic value. We continue to allocate our capital to higher growth markets and new opportunities that create competitive advantages and capitalize on the long-term trends in healthcare: namely, the desire to improve clinical outcomes; the growing demand for expanded access to care; and the optimization of cost and efficiency within healthcare systems. For the nine months ended January 25, 2019,

total net sales were affected by the divestiture of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses within the Minimally Invasive Therapies Group on July 29, 2017.

We continue to see an acceleration in our innovation cycle within our therapy innovation growth strategy. Our segments invest in a pipeline of groundbreaking medical technology, with several recent product launches and adoption of new therapies contributing to net sales growth. We remain focused on our globalization strategy, as net sales in emerging markets grew 7 percent during the three and nine months ended January 25, 2019, as compared to the corresponding periods in the prior fiscal year. Our emerging market performance continues to benefit from geographic diversification, with strong, balanced results around the world. Finally, in our third growth strategy, economic value, we continue to execute our value-based healthcare signature programs and aggressively develop unique, value-based healthcare solutions that directly link our therapies to improving outcomes and deliver improved economic value to the payers and providers. We remain focused on leading the shift to healthcare payment systems that reward value and improved patient outcomes over volume.

Segment and Market Geography

The tables below includes net sales by market geography for each of our segments for the three and nine months ended January 25, 2019 and January 26, 2018:

	U.S.[1]			Non-U.S. Developed Markets[2]			Emerging Markets[3]		
	Three months ended			Three months ended			Three months ended		
(in millions)	January 25, 2019	January 26, 2018	% Change	January 25, 2019	January 26, 2018	% Change	January 25, 2019	January 26, 2018	% Change
Cardiac and Vascular Group	$ 1,369	$ 1,395	(2)%	$ 924	$ 934	(1)%	$ 493	$ 471	5%
Minimally Invasive Therapies Group	930	862	8	796	807	(1)	398	372	7
Restorative Therapies Group	1,354	1,300	4	435	429	1	237	215	10
Diabetes Group	348	355	(2)	213	185	15	49	44	11
Total	$ 4,001	$ 3,912	2 %	$ 2,368	$ 2,355	1 %	$ 1,177	$ 1,102	7%

	U.S.[1]			Non-U.S. Developed Markets[2]			Emerging Markets[3]		
	Nine months ended			Nine months ended			Nine months ended		
(in millions)	January 25, 2019	January 26, 2018	% Change	January 25, 2019	January 26, 2018	% Change	January 25, 2019	January 26, 2018	% Change
Cardiac and Vascular Group	$ 4,240	$ 4,151	2 %	$ 2,766	$ 2,716	2 %	$ 1,449	$ 1,352	7%
Minimally Invasive Therapies Group	2,659	2,902	(8)	2,396	2,455	(2)	1,168	1,122	4
Restorative Therapies Group	4,005	3,779	6	1,275	1,217	5	688	620	11
Diabetes Group	1,006	856	18	619	521	19	140	118	19
Total	$ 11,910	$ 11,688	2 %	$ 7,056	$ 6,909	2 %	$ 3,445	$ 3,212	7%

(1) U.S. includes the United States and U.S. territories.
(2) Non-U.S. developed markets include Japan, Australia, New Zealand, Korea, Canada, and the countries of Western Europe.
(3) Emerging markets include the countries of the Middle East, Africa, Latin America, Eastern Europe, and the countries of Asia that are not included in the non-U.S. developed markets, as defined above.

Net sales increases in the U.S. for the three months ended January 25, 2019 were primarily attributable to strong growth in our Minimally Invasive Therapies Group and Restorative Therapies Group, partially offset by declines in our Cardiac and Vascular Group and Diabetes Group. Net sales increases in the U.S. for the nine months ended January 25, 2019 were primarily attributable to our Diabetes Group and Restorative Therapies Group, partially offset by the impact of the divestiture of our Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses within the Minimally Invasive Therapies Group on July 29, 2017. Net sales growth in non-U.S. developed markets for the three and nine months ended January 25, 2019 was primarily attributable to strong growth in our Diabetes Group, along with consistent growth across our segments in Japan and, for the nine months ended January 25, 2019, Western Europe. Net sales growth in emerging markets continues to reflect our broad diversification and was driven by strong performance in China, the Middle East & Africa, Eastern Europe, and both South and Southeast Asia. Currency had an unfavorable effect on net sales of $149 million and $166 million for the three and nine months ended January 25, 2019, respectively.

Looking ahead, our segments are likely to face competitive product launches and pricing pressure, geographic macro-economic risks, certain reimbursement challenges, impacts from changes in the mix of our product offerings, the timing of product approvals, replacement cycle challenges, and fluctuations in currency exchange rates. Additionally, changes in procedural volumes could affect our Cardiac and Vascular, Minimally Invasive Therapies, and Restorative Therapies Groups.

Cardiac and Vascular Group

The Cardiac and Vascular Group's products include pacemakers, insertable and external cardiac monitors, cardiac resynchronization therapy devices (CRT-D), implantable cardioverter defibrillators (ICD), leads and delivery systems, ventricular assist systems, ablation products, electrophysiology catheters, products for the treatment of atrial fibrillation, information systems for the management of patients with Cardiac Rhythm & Heart Failure devices, products designed to reduce surgical site infections, coronary and peripheral stents and related delivery systems, balloons and related delivery systems, endovascular stent graft systems,

heart valve replacement technologies, cardiac tissue ablation systems, and open heart and coronary bypass grafting surgical products. The Cardiac and Vascular Group also includes Care Management Services and Cath Lab Managed Services (CLMS) within the Cardiac Rhythm & Heart Failure division. The Cardiac and Vascular Group's net sales for the three and nine months ended January 25, 2019 were $2.8 billion and $8.5 billion, respectively, a decrease of 1 percent and an increase of 3 percent, respectively, as compared to the corresponding periods in the prior fiscal year. Currency had an unfavorable impact on net sales for the three and nine months ended January 25, 2019 of $60 million and $62 million, respectively. The Cardiac and Vascular Group's net sales for the three and nine months ended January 25, 2019, as compared to the corresponding periods in the prior fiscal year, had net sales growth in Coronary & Structural Heart and Aortic, Peripheral & Venous (formerly known as Aortic & Peripheral Vascular) divisions, offset by declines in Cardiac Rhythm & Heart Failure. See the more detailed discussion of each division's performance below.

Cardiac Rhythm & Heart Failure net sales for the three and nine months ended January 25, 2019 were $1.4 billion and $4.3 billion, respectively, a decrease of 4 percent and flat, respectively, as compared to the corresponding periods in the prior fiscal year. Cardiac Rhythm & Heart Failure net sales decrease for the three and nine months ended January 25, 2019 was driven by declines in Heart Failure, Care Management Services, and CLMS, offset by growth in Arrhythmia Management. The decline in Heart Failure was driven by CRT-D replacements and LVAD headwinds due to a competitor product launch in the U.S. and changes in the U.S. heart transplant guidelines. The growth in Arrhythmia Management was driven by AF Solutions and Pacing, due to the continued strong adoption of the Micra transcatheter pacing system and Azure wireless pacemaker. Arrhythmia Management net sales growth also benefited from strong adoption of the TYRX absorbable antibacterial envelope through further expansion of value-based health-care arrangements.

Coronary & Structural Heart net sales for the three and nine months ended January 25, 2019 were $913 million and $2.7 billion, respectively, an increase of 3 percent and 7 percent, respectively, as compared to the corresponding periods in the prior fiscal year. Coronary & Structural Heart net sales growth for the three and nine months ended January 25, 2019 was driven by the global strength of the CoreValve Evolut PRO transcatheter aortic valve system (Evolut PRO) and continued penetration into intermediate risk in the U.S., as well as growth in cannulae, including the Bio-Medicus Next Gen Cannulae, guide catheters, and coronary balloons. For the three months ended January 25, 2019, net sales growth was partially offset by declines in drug-eluting stents in international markets. For the nine months ended January 25, 2019, net sales growth also benefited from growth in drug-eluting stents, including growth in the U.S. from Resolute Onyx.

Aortic, Peripheral & Venous net sales for the three and nine months ended January 25, 2019 were $476 million and $1.4 billion, respectively, an increase of 4 percent and 6 percent, respectively, as compared to the corresponding periods in the prior fiscal year. Aortic, Peripheral & Venous net sales growth for the three and nine months ended January 25, 2019 was driven by strong performance of the VenaSeal vein closure system, for which final approval for reimbursement payment in the U.S. from the Centers for Medicare & Medicaid Services (CMS) was received in January 2018. Net sales growth for the three and nine months ended January 25, 2019 was also attributable to growth in Percutaneous Transluminal Angioplasty (PTA) balloons and drug-coated balloon growth in international markets, driven by our recent launch of IN.PACT Admiral drug-coated balloon in Japan. For the three months ended January 25, 2019, net sales growth was also driven by the launch of the Valiant Navion thoracic stent graft system which received U.S. FDA and CE Mark approval in October and November 2018, respectively.

Looking ahead, we expect our Cardiac and Vascular Group could be affected by the following:

- Acceptance and growth from penetration of the self-expanding CoreValve Evolut transcatheter aortic valve replacement platform into intermediate risk indication in the U.S.

- Continued acceptance and growth from Evolut PRO, which provides industry-leading hemodynamics, reliable delivery, and advanced sealing with an excellent safety profile. Evolut PRO received CE Mark approval at the end of the first quarter of fiscal year 2018 and launched in Europe during the second quarter of fiscal year 2018. Evolut PRO launched in Japan and received approval from the Ministry of Health, Labour, and Welfare during the second quarter of fiscal year 2019.

- Continued acceptance and growth of the CRT-P quadripolar pacing system.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

- Continued acceptance and growth of the Claria MRI CRT-D system with EffectivCRT Diagnostic and Effective CRT during AF algorithm, which launched in Japan during the third quarter of fiscal year 2018.

- Continued growth of our Micra transcatheter pacing system. Micra is a miniaturized single chamber pacemaker system that is delivered through the femoral vein and is implanted in the right ventricle of the heart. The system does not use a lead and does not have a subcutaneous device pocket underneath the skin as with conventional pacemaker systems. We received final approval for reimbursement in the U.S. from the CMS and in Japan from

the Ministry of Health, Labour, and Welfare during the fourth quarter of fiscal year 2017 and during the second quarter of fiscal year 2018, respectively, for this transformative therapy, which we expect will continue to accelerate sales in the U.S. and in Japan.

- Continued acceptance and growth from the Azure XT and S SureScan pacing systems, which launched in the U.S. during the third quarter of fiscal year 2018. Azure pacemakers feature Medtronic-exclusive BlueSync technology, which enables automatic, secure wireless remote monitoring with increased device longevity.

- Continued acceptance of the HVAD System as a Destination Therapy for patients with advanced heart failure who are not candidates for heart transplants. The HVAD System, a left ventricular assist device or LVAD, helps the heart pump and increases the amount of blood that flows through the body. In the U.S., we received FDA approval for the Destination Therapy indication in September 2017 and the thoracotomy indication in July 2018, which allows for a less-invasive implant via a small surgical incision between the patient's ribs on the left side of the chest. We expect that future LVAD net sales will be impacted by a competitor's product launch and the impact of changes in the U.S. heart transplant guidelines. Further, we anticipate launching the HVAD system in Japan during the fourth quarter of fiscal year 2019.

- Continued acceptance and growth from Care Management Services as post-acute care services become even more critical in bundled payment models for different interventions or therapies.

- Continued acceptance and growth from the market release of Resolute Onyx. Resolute Onyx builds on the Resolute Integrity drug-eluting coronary stent with thinner struts to improve deliverability and is the first stent to feature our CoreWire technology, allowing greater visibility during procedures.

- Continued acceptance and growth of the IN.PACT Admiral drug-coated balloon for the treatment of peripheral artery disease in the upper leg.

- Continued acceptance and growth from the VenaSeal vein closure system in the United States, for which reimbursement payment was established in January 2018 and payer coverage has been gradually increasing. The VenaSeal system is a unique non-thermal solution to address superficial venous disease that provides improved patient comfort, reduces the recovery time, and eliminates the risk of thermal nerve injury.

- Continued acceptance and growth from the Valiant family of thoracic stent grafts, including the Valiant Navion which received U.S. FDA approval in October 2018 and CE Mark approval in November 2018.

- Continued acceptance and growth from the expansion of the Endurant II used with the Heli-FX EndoAnchor for the short neck indication in the U.S., which received FDA approval in October 2017.

Minimally Invasive Therapies Group

The Minimally Invasive Therapies Group's products span the entire continuum of patient care from diagnosis to recovery, with a focus on diseases of the gastrointestinal tract, lungs, pelvic region, kidneys, obesity, and preventable complications. The products include those for advanced and general surgical care including surgical stapling devices, vessel sealing instruments, wound closure, electrosurgery products, hernia mechanical devices, mesh implants, advanced ablation, interventional lung, ventilators, capnography, airway products, sensors, dialysis, and monitors. Net sales for the three months ended July 28, 2017 also include sales of dental and animal health, chart paper, wound care, incontinence, electrodes, SharpSafety, thermometry, perinatal protection, blood collection, compression, and enteral feeding offerings, which were divested on July 29, 2017.

The Minimally Invasive Therapies Group's net sales for the three and nine months ended January 25, 2019 were $2.1 billion and $6.2 billion, respectively, an increase of 4 percent and a decrease of 4 percent, respectively, as compared to the corresponding periods in the prior fiscal year. Currency had an unfavorable impact on net sales for the three and nine months ended January 25, 2019 of $52 million and $68 million, respectively. The Minimally Invasive Therapies Group's net sales for the nine months ended January 26, 2018 were affected by the divestiture of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses on July 29, 2017.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

During the second quarter of fiscal year 2018, after the divestiture discussed above, the Surgical Solutions and Patient Monitoring & Recovery divisions were realigned into the Surgical Innovations and Respiratory, Gastrointestinal, & Renal divisions. The Surgical Innovations division consists of the Advanced Surgical and General Surgical businesses. The Advanced Surgical business includes the Advanced Stapling, Advanced Energy, Hernia, Gynecology, and Lung Health product lines. The General Surgical business includes the Wound Closure, Electrosurgery, and Instruments product lines.

The Respiratory, Gastrointestinal, & Renal division consists of the Respiratory & Monitoring Solutions, GI Solutions, and Renal Care Solutions businesses. The Respiratory & Monitoring Solutions business includes the Patient Monitoring, Respiratory Interventions, Advanced Ablation, and GI Solutions product lines. The Renal Care Solutions business includes the Renal Access and Dialyzers product lines.

Surgical Innovations net sales for the three and nine months ended January 25, 2019 were $1.4 billion and $4.2 billion, respectively, an increase of 4 percent and 5 percent, respectively, as compared to the corresponding periods in the prior fiscal year. Surgical Innovations net sales growth was driven by new products in Advanced Energy and Advanced Stapling, led by the LigaSure vessel sealing instruments with nano-coating, Exact and L-Hook, and both the Tri-Staple 2.0 endo stapling specialty reloads and Signia powered stapler.

Respiratory, Gastrointestinal, & Renal net sales for the three and nine months ended January 25, 2019 were $690 million and $2.0 billion, respectively, an increase of 5 percent and a decrease of 19 percent, respectively, as compared to the corresponding periods in the prior fiscal year. Respiratory, Gastrointestinal, & Renal net sales for the three and nine months ended January 25, 2019 benefited from growth in Respiratory and Patient Monitoring, including the continued adoption of MicroStream capnography monitoring products and growth in ventilators and pulse oximetry products. Also driving growth for the three and nine months ended January 25, 2019 was growth in GI and Hepatology and strength in renal access products. Net sales performance in Respiratory, Gastrointestinal, & Renal for the nine months ended January 25, 2019 declined as a result of the July 29, 2017 divestiture of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses.

Looking ahead, we expect our Minimally Invasive Therapies Group could be affected by the following:

- Continued acceptance and future growth of Open-to-MIS techniques and tools supported by our efforts to transition open surgery to MIS. The Open-to-MIS initiative focuses on furthering our presence in and working to optimize open surgery globally, while capturing the market opportunity that exists in transitioning open procedures to MIS, whether through traditional MIS, or advanced technologies including robotics.

- Continued acceptance and future growth of the powered stapling and energy platform, along with our ability to execute ongoing strategies to develop, gain regulatory approval, and commercialize new products including our surgical robotics platform.

- Our ability to obtain adequate replacement sterilization capacity in our Surgical Innovations business in light of the Illinois Environmental Protection Agency's (Illinois EPA) decision to close the Sterigenics U.S. LLC (Sterigenics) Willowbrook, Illinois facility on February 15, 2019.

- The July 29, 2017 divestiture of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses. Net sales of the businesses included in the divestiture were $0.6 billion for the three months ended July 28, 2017. We have entered into Transition Manufacturing Agreements (TMAs) with Cardinal Health, Inc. (Cardinal). The TMAs will contribute to net sales and are designed to ensure and facilitate an orderly transfer of business operations for a transition period of two to five years, with the ability to extend upon mutual agreement of the parties.

- Our ability to execute ongoing strategies in order to address the competitive pressure of reprocessing of our vessel sealing disposables in the U.S.

- Our ability to create markets and drive product and procedures into emerging markets. We have high quality and cost-effective surgical products designed for customers in emerging markets such as the ValleyLab LS10 single channel vessel sealing generator, which is compatible with our line of LigaSure instruments and designed for simplified use and affordability.

- Continued acceptance and future growth within the end stage renal disease market. The population of patients treated for end stage renal disease globally is expected to double over the next decade. We will grow our therapy innovation with scalable and affordable dialysis delivery while investing in vascular creation and maintenance technologies. In addition, the HD multi-pass system reduces infrastructure by requiring less water, less start-up costs, and offers high quality ultrapure dialysate treatment. We are expecting regulatory filing in late fiscal year 2020, with launch following regulatory clearance in targeted countries.

- Continued elevation of the standard of care for respiratory compromise, a progressive condition impacting a patient's ability to breathe effectively.

- Continued acceptance and growth in respiratory care, airway and ventilation management, and Patient Monitoring. Key products in this area include the Puritan Bennett 980 ventilator, Microstream Capnography

bedside capnography monitor, portable monitor with Nellcor pulse oximetry system with OxiMax technology and the Nellcor Respiratory Compromise monitor with vital signs of SpO2, pulse rate, End-Tidal CO2, and Respiratory Rate.

- Continued and future acceptance of less invasive standards of care, including the areas of GI Solutions and Advanced Ablation. Recently launched products include the PillCam COLON capsule endoscopy, the Barrx platform through ablation with the Barrx 360 Express catheter, Bravo Calibration-free reflux testing, and the Emprint ablation system with Thermosphere Technology, which maintains predictable spherical ablation zones throughout procedures reducing procedure time and cost.
- Continued and future acceptance of Interventional Lung Solutions. Products include the superDimension GenCut core biopsy system and the Triple Needle Cytology Brush, a lung tissue biopsy tool for use with the superDimension navigation system. The superDimension system enables a minimally invasive approach to accessing difficult-to-reach areas of the lung, which may aid in the diagnosis of lung cancer.
- Expanding the use of less invasive treatments and furthering our commitment to improving options for women with abnormal uterine bleeding. Our expanded and strengthened surgical offerings are expected to complement our global gynecology business.

Restorative Therapies Group

The Restorative Therapies Group's products focus on various areas of the spine, bone graft substitutes, biologic products, trauma, implantable neurostimulation therapies and drug delivery systems for the treatment of chronic pain, movement disorders, epilepsy, overactive bladder, urinary retention, fecal incontinence and gastroparesis, as well as products to treat conditions of the ear, nose, and throat (ENT), and systems that incorporate advanced energy surgical instruments. The Restorative Therapies Group also manufactures and sells image-guided surgery and intra-operative imaging systems, robotic guidance systems used in robot assisted spine procedures, and therapies to treat diseases of the vasculature in and around the brain, including coils, neurovascular stents and flow diversion products. The Restorative Therapies Group's net sales for the three and nine months ended January 25, 2019 were $2.0 billion and $6.0 billion, respectively, an increase of 4 percent and 6 percent, respectively, as compared to the corresponding periods in the prior fiscal year. Currency had an unfavorable impact on net sales for the three and nine months ended January 25, 2019 of $25 million and $23 million, respectively. Net sales growth for the three and nine months ended January 25, 2019 was driven by the Brain Therapies, Specialty Therapies, and Pain Therapies divisions. See the more detailed discussion of each division's performance below.

Spine net sales for the three and nine months ended January 25, 2019 were $655 million and $2.0 billion, respectively, a decrease of 1 percent for the three months ended January 25, 2019 and flat for the nine months ended January 25, 2019. However, our Surgical Synergy strategy, which integrates our spinal implants with enabling technologies such as imaging, navigation, power instruments, nerve monitoring and Mazor robotics, resulted in spine enabling technologies contributing to the strong performance in our Neurosurgery business. Additionally, in line with our "Speed-to-Scale" initiative, which involves faster innovation cycles and the launching of a steady cadence of new products at scale with sets immediately available for the entire market, recently launched products including the Infinity OCT System and the Solera Voyager 5.5/6.0 fixation system contributed to net sales during the period.

Brain Therapies net sales for the three and nine months ended January 25, 2019 were $650 million and $1.9 billion, respectively, an increase of 11 percent as compared to the corresponding periods in the prior fiscal year. Brain Therapies net sales growth was driven by strong growth in both Neurovascular and Neurosurgery. Neurovascular net sales growth was driven by strength across our stroke franchise, with growth across our stent retriever, flow diversion, neuro access, and embolic protection products. Neurosurgery net sales growth was driven by strong capital equipment sales of the StealthStation S8 surgical navigation systems, Mazor X robotic guidance systems, O-Arm Imaging Systems, and Midas Rex powered surgical instrument systems. Additionally, Neurosurgery net sales growth for the nine months ended January 25, 2019 benefited from strong sales of Visualase MRI-guided laser ablation systems.

Specialty Therapies net sales for the three and nine months ended January 25, 2019 were $407 million and $1.2 billion, respectively, an increase of 2 and 6 percent, respectively, as compared to the corresponding periods in the prior fiscal year. Net sales growth was driven by strong sales of the Aquamantys biopolar sealers within Transformative Solutions and growth in ENT.

Pain Therapies net sales for the three and nine months ended January 25, 2019 were $314 million and $942 million, respectively, an increase of 5 and 13 percent, respectively, as compared to the corresponding periods in the prior fiscal year. The increase in net sales was driven by our Intellis spinal cord stimulation platform which received U.S. FDA approval in September 2017 and CE Mark in November 2017. Further driving net sales growth were the Evolve workflow algorithm, Snapshot reports, and our Targeted Drug Delivery products.

Looking ahead, we expect our Restorative Therapies Group could be affected by the following:

- Continued acceptance and growth of the Solitare FR revascularization device for treatment of acute ischemic stroke and the Pipeline Embolization Devices, endovascular treatments for large or giant wide-necked brain aneurysms.
- Acceptance of our React Catheter and Riptide aspiration system, along with the expected launch of our next-generation Solitaire revascularization device.
- Continued growth from Neurosurgery StealthStation and O-Arm Imaging Systems, Midas, and ENT Navigation and Power Systems.
- Continued sales of Mazor robotic units and associated market adoption of robot-assisted spine procedures, including the Mazor X Stealth, our integrated robotics and navigation platform, which received FDA approval in November 2018.
- Strengthening of our position as a global leader in enabling technologies for spine surgery as a result of the December 2018 acquisition of Mazor Robotics.
- Continued market acceptance of our integrated solutions through the Surgical Synergy strategy, which integrates our spinal implants with enabling technologies such as imaging, navigation, power instruments, nerve monitoring and Mazor robotics.
- Continued success of our "Speed-to-Scale" program launches, which involves faster innovation cycles and launching a steady cadence of new products at scale with sets immediately available for the entire market.
- Market acceptance and continued global adoption of innovative new Spine products, such as our Infinity OCT System and Solera Voyager 5.5/6.0 fixation system, as well as our CD Horizon Solera Voyager system, our ELEVATE expandable interbody cages, and our OLIF25 and OLIF51 procedural solutions.
- Growth in the broader vertebral compression fracture (VCF) and adjacent markets, as we continue to pursue the development of other therapies to treat more patients with VCF, including continued success of both the Kyphon V vertebroplasty system and the Osteocool RF Spinal Tumor ablation system.
- Continued market acceptance and global adoption of our Intellis spinal cord stimulator, Evolve workflow algorithm, and Snapshot reporting to treat chronic pain in major markets around the world.
- Ongoing obligations under the U.S. FDA consent decree entered in April 2015 relating to the SynchroMed drug infusion system and the Neuromodulation quality system. The U.S. FDA lifted its distribution requirements on our implantable drug pump in October and its warning letter in November 2017.
- Continued acceptance of our devices for the treatment of Parkinson's Disease, epilepsy and other movement disorders.
- Continued acceptance and growth of our Specialty Therapies, including InterStim therapy for the treatment of the symptoms of overactive bladder, urinary retention, and bowel incontinence, and Transformative Solutions core portfolio products including Aquamantys biopolar sealers, PlasmaBlade soft tissue dissection devices and Radialux lighted retractors.

Diabetes Group

The Diabetes Group's products include insulin pumps, continuous glucose monitoring (CGM) systems, insulin pump consumables, and therapy management software. The Diabetes Group's net sales for the three and nine months ended January 25, 2019 were $610 million and $1.8 billion, respectively, an increase of 4 percent and 18 percent, respectively, as compared to the corresponding periods in the prior fiscal year. Currency had an unfavorable impact on net sales for the three and nine months ended January 25, 2019 of $12 million and $13 million, respectively. The Diabetes Group's net sales growth for the three and nine months ended January 25, 2019 was primarily attributable to the continued demand for the MiniMed 670G hybrid closed loop system, which offers the latest in SmartGuard technology, as well as the higher sensor attachment and utilization we are seeing with our integrated CGM users. Further, we experienced continued international growth due to strong sales of insulin pump systems in Europe, Latin America, and Asia Pacific as well as worldwide strength of the Guardian Connect CGM system.

Looking ahead, we expect our Diabetes Group could be affected by the following:

- Continued patient demand for the MiniMed 670G system, the first hybrid closed loop system in the world. The system features our most advanced SmartGuard algorithm, which enables improved glucose control with reduced user input. Over 157,000 trained, active users are benefiting from SmartGuard technology.
- Continued acceptance and future growth internationally for the MiniMed 670G system. This system received CE mark in June 2018 and is now commercialized in Canada, Australia, Chile and in select European countries. The global adoption of sensor-augmented insulin pump systems has resulted in strong sensor attachment rates.
- Changes in medical reimbursement policies and programs, along with additional payor coverage of the MiniMed 670G system.
- Acceptance of the upcoming launch of our advanced hybrid closed loop system, along with the advancement of our Personalized Closed Loop system which was just granted "Breakthrough Device" designation by the FDA. These technologies feature our next-generation algorithms designed to improve time-in-range by further automating insulin delivery.
- Continued acceptance and future growth of the MiniMed 640G system with SmartGuard Suspend before Low technology, which has launched in Europe, Australia, and select countries in Latin America and Asia. The MiniMed 640G system received regulatory approval in Japan in the fourth quarter of fiscal year 2018.
- Continued acceptance and growth of the Guardian Connect CGM system which displays glucose information directly to a smartphone. This system has launched internationally and now in the U.S after receiving FDA approval in the fourth quarter of fiscal year 2018.
- Continued partnership with UnitedHealthcare as the preferred in-network provider of insulin pumps, giving their members, including pediatric patients 7 years and above, access to our advanced diabetes technology and comprehensive support services.
- Continued partnership and future growth of our outcomes-based agreement with select health plans (i.e. Aetna), where a component of our pump reimbursement is based on successfully meeting clinical improvement thresholds as part of our value-based healthcare solutions.

CRITICAL ACCOUNTING ESTIMATES

We have used various accounting policies to prepare the consolidated financial statements in accordance with U.S. GAAP. Our significant accounting policies are disclosed in Note 1 to the consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended April 27, 2018.

The preparation of the consolidated financial statements, in conformity with U.S. GAAP, requires us to use judgment in making estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, and expenses. These estimates reflect our best judgment about economic and market conditions and the potential effects on the valuation and/or carrying value of assets and liabilities based upon relevant information available. We base our estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

Our critical accounting estimates include the following:

Litigation Contingencies We are involved in a number of legal actions involving product liability, intellectual property and commercial disputes, shareholder related matters, environmental proceedings, income tax disputes, and governmental proceedings and investigations. The outcomes of these legal actions are not completely within our control and may not be known for prolonged periods of time. In some actions, the enforcement agencies or private claimants seek damages, as well as other civil or criminal remedies (including injunctions barring the sale of products that are the subject of the proceeding), that could require significant expenditures or result in lost revenues or limit our ability to

conduct business in the applicable jurisdictions. Estimating probable losses from our litigation and governmental proceedings is inherently difficult, particularly when the matters are in early procedural stages, with incomplete scientific facts or legal discovery; involve unsubstantiated or indeterminate claims for damages; potentially involve penalties, fines, or punitive damages; or could result in a change in business practice. Our significant legal proceedings are discussed in Note 17 to the current period's consolidated financial statements.

Income Tax Reserves and U.S. Tax Reform We establish reserves when, despite our belief that our tax return positions are fully supportable, we believe that certain positions are likely to be challenged and that we may or may not prevail. Under U.S. GAAP, if we determine that a tax position is more likely than not of being sustained upon audit, based solely on the technical

merits of the position, we recognize the benefit. We measure the benefit by determining the amount that is greater than 50 percent likely of being realized upon settlement. We presume that all tax positions will be examined by a taxing authority with full knowledge of all relevant information. The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations in a multitude of jurisdictions across our global operations. We regularly monitor our tax positions and tax liabilities. We reevaluate the technical merits of our tax positions and recognize an uncertain tax benefit, or derecognize a previously recorded tax benefit, when there is (i) a completion of a tax audit, (ii) effective settlement of an issue, (iii) a change in applicable tax law including a tax case or legislative guidance, or (iv) the expiration of the applicable statute of limitations. Significant judgment is required in accounting for tax reserves. Although we believe that we have adequately provided for liabilities resulting from tax assessments by taxing authorities, positions taken by these tax authorities could have a material impact on our effective tax rate, consolidated earnings, financial position and/or cash flows.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation, commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"), which significantly revised U.S. corporate income taxation by, among other things, lowering the U.S. corporate income tax rate, broadening the base of taxation, and implementing a territorial tax system. We had a measurement period of up to one year after the enactment date of the Tax Act to finalize the recognition of the related tax impacts. The measurement period closed during the three months ended January 25, 2019.

Valuation of Intangible Assets and Goodwill When we acquire a business, the assets acquired and liabilities assumed are recorded at their respective fair values at the acquisition date. Goodwill is the excess of the purchase price consideration over the estimated fair value of net assets of acquired businesses. Intangible assets primarily include patents, trademarks, tradenames, customer relationships, purchased technology, and IPR&D. Determining the fair value of intangible assets acquired as part of a business combination requires us to make significant estimates. These estimates include the amount and timing of projected future cash flows of each project or technology, the discount rate used to discount those cash flows to present value, the assessment of the asset's life cycle, and the consideration of legal, technical, regulatory, economic, and competitive risks.

The test for goodwill impairment requires us to make several estimates to determine fair value, most of which are based on projected future cash flows. Our estimates associated with the goodwill impairment test are considered critical due to the amount of goodwill recorded on our consolidated balance sheets and the judgment required in determining fair value, including projected future cash flows. We assess the impairment of goodwill at the reporting unit level annually in the third quarter and whenever an event occurs or circumstances change that would indicate that the carrying amount may be impaired.

We test definite-lived intangible assets for impairment when an event occurs or circumstances change that would indicate the carrying amount of the assets or asset group may be impaired. Our tests are based on future cash flows that require significant judgment with respect to future revenue and expense growth rates, appropriate discount rates, asset groupings, and other assumptions and estimates. We use estimates that are consistent with our business plans and a market participant's view of the assets being evaluated. Actual results may differ from our estimates due to a number of factors including, among others, changes in competitive conditions, timing of regulatory approval, results of clinical trials, changes in worldwide economic conditions, and fluctuations in currency exchange rates.

We assess the impairment of indefinite-lived intangible assets annually in the third quarter and whenever an event occurs or circumstances change that would indicate that the carrying amount may be impaired. Our impairment tests of indefinite-lived intangible assets require us to make several estimates to determine fair value, including projected future cash flows and discount rates.

NEW ACCOUNTING PRONOUNCEMENTS

Information regarding new accounting pronouncements is included in Note 2 to the current period's consolidated financial statements.

ACQUISITIONS

Information regarding acquisitions is included in Note 4 to the current period's consolidated financial statements.

COSTS AND EXPENSES

The following is a summary of cost of products sold, research and development, and selling, general, and administrative expenses as a percent of net sales:

	Three months ended		Nine months ended	
	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Cost of products sold	30.0%	29.8%	29.8%	30.6%
Research and development expense	7.4%	7.6%	7.7%	7.6%
Selling, general, and administrative expense	34.4%	34.2%	34.8%	35.0%

Cost of Products Sold We continue to focus on reducing our costs of production through supplier management, manufacturing improvements, and optimizing our manufacturing network.

Cost of products sold for the three and nine months ended January 25, 2019 was $2.3 billion and $6.7 billion, respectively. The increase in cost of products sold as a percentage of net sales for the three months ended January 25, 2019, as compared to the corresponding period in the prior fiscal year, was driven by restructuring and associated costs, a change in product mix due to strong growth in some of our lower margin businesses, and pricing pressures. Cost of products sold for the three months ended January 25, 2019 includes $21 million of restructuring and associated costs, as compared to $13 million for the three months ended January 26, 2018.

The decrease in cost of products sold as a percentage of net sales for the nine months ended January 25, 2019, as compared to the corresponding period in the prior fiscal year, was favorably affected by the divestiture of lower-margin products in conjunction with the divestiture of our Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses on July 29, 2017. Also contributing to the decrease in cost of products sold as a percentage of net sales for the nine months ended January 25, 2019 was the infusion set recall in our Diabetes Group, along with $17 million of costs recognized in relation to restoring operations at our four Puerto Rico manufacturing sites after Hurricane Maria, including idle facility costs, asset write-downs, and other facility-related costs, incurred during the nine months ended January 26, 2018. These benefits were slightly offset by increased restructuring and associated costs. Cost of products sold for the nine months ended January 25, 2019 includes $58 million of restructuring and associated costs, as compared to $25 million for the nine months ended January 26, 2018.

Research and Development Expense Research and development expense for the three and nine months ended January 25, 2019 was $561 million and $1.7 billion, respectively. We remain committed to accelerating the development of meaningful innovations to deliver better patient outcomes at appropriate costs that lead to enhanced quality of life and may be validated by clinical and economic evidence. We are also focused on expanding access to quality healthcare.

Selling, General, and Administrative Expense Our goal is to continue to leverage selling, general, and administrative expense initiatives and to continue to realize cost synergies expected from our acquisitions. Selling, general, and administrative expense primarily consists of salaries and wages, other administrative costs, such as professional fees and marketing expenses, and certain acquisition, restructuring, and divestiture-related expenses.

Selling, general, and administrative expense for the three and nine months ended January 25, 2019 was $2.6 billion and $7.8 billion, respectively. The increase in selling, general, and administrative expense as a percentage of net sales for the three months ended January 25, 2019, as compared to the corresponding period in the prior fiscal year, was driven by acquisition-related items and restructuring and associated costs. Selling, general, and administrative expense for the three months ended January 25, 2019 includes $77 million of acquisition-related items, as compared to $21 million for the three months ended January 26, 2018. Additionally, selling, general, and administrative expense for the three months ended January 25, 2019 includes $19 million of restructuring and associated costs, as compared to $10 million for the three months ended January 26, 2018.

The decrease in selling, general, and administrative expense as a percentage of net sales for the nine months ended January 25, 2019, as compared to the corresponding period in the prior fiscal year, was favorably affected by $115 million of expenses incurred in connection with the divestiture of our Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses during the nine months ended January 26, 2018. This benefit was partially offset by increased acquisition-related items, as well as increased restructuring and associated costs. Selling, general, and administrative expense for the nine months ended January 25, 2019 includes $120 million of acquisition-related items, as compared to $97 million for the nine months ended January 26, 2018. Additionally, selling, general, and administrative expense for the nine months ended January 25, 2019 includes $86 million of restructuring and associated costs, as compared to $14 million for the nine months ended January 26, 2018.

The following is a summary of other costs and expenses:

	Three months ended		Nine months ended	
(in millions)	January 25, 2019	January 26, 2018	January 25, 2019	January 26, 2018
Amortization of intangible assets	$ 436	$ 461	$ 1,327	$ 1,375
Restructuring charges, net	26	7	112	23
Certain litigation charges	63	61	166	61
Gain on sale of businesses	—	—	—	(697)
Other operating expense, net	57	128	278	360
Other non-operating (income) expense, net	(71)	139	(309)	(67)
Interest expense	243	270	726	829

Amortization of Intangible Assets Amortization of intangible assets includes the amortization expense of our definite-lived intangible assets, consisting of purchased patents, trademarks, tradenames, customer relationships, purchased technology, and other intangible assets. Amortization expense was $436 million and $1.3 billion for the three and nine months ended January 25, 2019, respectively, as compared to $461 million and $1.4 billion for the three and nine months ended January 26, 2018, respectively. The decrease in amortization expense for the three and nine months ended January 25, 2019 as compared to the corresponding periods in the prior fiscal year is primarily driven by several patents that became fully amortized during fiscal year 2019.

Restructuring Charges, Net

Enterprise Excellence

In the third quarter of fiscal year 2018, we announced a multi-year global Enterprise Excellence Program designed to drive long-term business growth and sustainable efficiency. The Enterprise Excellence Program is expected to further leverage our global size and scale as well as enhance the customer and employee experience.

The Enterprise Excellence Program is focused on three objectives:

- Global Operations - integrating and enhancing global manufacturing and supply processes, systems and site presence to improve quality, delivery cost and cash flow
- Functional Optimization - enhancing and leveraging global operating models and systems across several enabling functions to improve productivity and employee experience
- Commercial Optimization - optimizing certain processes, systems and models to improve productivity and the customer experience

The Enterprise Excellence Program is designed to drive operating margin improvement as well as fund investment in strategic growth initiatives, with expected annual gross savings of more than $3.0 billion from cost reductions and leverage of our fixed infrastructure by the end of fiscal year 2022. Approximately $500 million to $700 million of gross annual savings are expected to be achieved each fiscal year through the end of fiscal year 2022.

The Enterprise Excellence Program is expected to result in pre-tax restructuring charges of approximately $1.6 billion to $1.8 billion, the vast majority of which are expected to be incurred by the end of fiscal year 2022 and result in cash outlays to be substantially complete by the end of fiscal year 2023. Approximately half of the estimated restructuring charges are related to employee termination benefits. The remaining restructuring charges are costs associated with the restructuring program, such as salaries for employees

supporting the program and consulting expenses. We expect these costs to be recognized within *restructuring charges, net, cost of products sold*, and *selling, general, and administrative expense* in the consolidated statements of income.

For the three and nine months ended January 25, 2019, we recognized restructuring charges of $69 million and $264 million, respectively. For the three and nine months ended January 25, 2019, restructuring charges included $29 million and $120 million, respectively, recognized within *restructuring charges, net* in the consolidated statements of income, primarily comprised of employee termination benefits. For the three and nine months ended January 25, 2019, restructuring charges also included costs incurred as a direct result of the restructuring program, such as salaries for employees supporting the program and consulting expenses, including $21 million and $58 million, respectively, recognized within *cost of products sold* and $19 million and $73 million, respectively, recognized within *selling, general, and administrative expense* in the consolidated statements of income. For the nine months ended January 25, 2019, *selling, general, and administrative expense* also includes $13 million of fixed asset write-downs.

For the three and nine months ended January 26, 2018, we recognized restructuring charges of $32 million, which included $9 million of employee termination benefits recognized within *restructuring charges, net* in the consolidated statements of income. Restructuring charges also included costs incurred as a direct result of the restructuring program, such as salaries for employees supporting the program and consulting expenses, including $13 million recognized within *cost of products sold* and $10 million recognized within *selling, general and administrative expense* in consolidated statements of income.

Cost Synergies

In the third quarter of fiscal year 2018, we achieved $850 million in cost synergies related to the acquisition of Covidien plc. The costs synergies related to administrative office optimization, manufacturing and supply chain infrastructure, and certain general and administrative savings. Cash outlays for the cost synergies program are scheduled to be substantially complete by the end of fiscal year 2019.

During the three and nine months ended January 25, 2019, we recognized no restructuring charges and accrual adjustments of $1 million and $8 million, respectively. Accrual adjustments relate to certain employees identified for termination finding other positions within Medtronic, cancellations of employee terminations, and employee termination benefits being less than initially estimated.

For the three months ended January 26, 2018, we recognized no restructuring charges, and for the nine months ended January 26, 2018, we recognized restructuring charges of $45 million. For the three and nine months ended January 26, 2018, we recognized accrual adjustments of $2 million and $15 million, respectively. Accrual adjustments relate to certain employees identified for termination finding other positions within Medtronic, cancellations of employee terminations, and employee termination benefits being less than initially estimated. For the nine months ended January 26, 2018, restructuring charges included $29 million of employee termination benefits recognized within *restructuring charges, net* in the consolidated statements of income. For the nine months ended January 26, 2018, restructuring charges also included other costs of $12 million within *cost of products sold* and $4 million recognized within *selling, general and administrative expense.*

For additional information about our restructuring programs, refer to Note 6 to the current period's consolidated financial statements.

Certain Litigation Charges We classify litigation charges and gains related to significant legal matters as certain litigation charges. During the three and nine months ended January 25, 2019, we recognized $63 million and $166 million, respectively, of litigation charges related to probable and estimable damages for significant legal matters. During the three and nine months ended January 26, 2018, we recognized $61 million of litigation charges related to probable and estimable damages for significant legal matters.

Gain on Sale of Businesses We recognized a pre-tax gain of $697 million on the sale of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses during the nine months ended January 26, 2018. There were no sales of businesses during the three months ended January 26, 2018 or the three and nine months ended January 25, 2019.

Other Operating Expense, Net Other operating expense, net includes royalty income and expense, Transition Service Agreement income, intangible asset charges, currency transaction and derivative gains and losses, contributions to the Medtronic Foundation, Puerto Rico excise taxes, changes in the fair value of contingent consideration, and charges associated with business exits. For the three and nine months ended January 25, 2019, other operating expense, net was $57 million and $278 million, respectively, as compared to $128 million and $360 million for the three and nine months ended January 26, 2018, respectively.

For the three months ended January 25, 2019, the decrease in other operating expense, net was driven by gains in our remeasurement and hedging programs, changes in the fair value of contingent consideration, and decreased IPR&D charges. Our remeasurement and hedging programs, combined, resulted in a gain of $36 million for the three months ended January 25, 2019 as compared to a loss of $44 million for the three months ended January 26, 2018. Changes in the fair value of contingent consideration resulted in gains of $59 million and $12 million for the three months ended January 25, 2019 and January 26, 2018, respectively. IPR&D charges were $11 million and $63 million for the three months ended January 25, 2019 and January 26, 2018, respectively. These benefits were partially offset by intangible asset and other charges of $69 million related to business exits during the three months ended January 25, 2019 and a reduction of Transition Service Agreement income.

For the nine months ended January 25, 2019, the decrease in other operating expense, net was driven by our remeasurement and hedging programs, which, combined, resulted in a gain of $9 million for the nine months ended January 25, 2019 and a loss of $81 million for the nine months ended January 26, 2018. Also contributing to the decrease in other operating expense, net were IPR&D charges, of which we recognized $26 million and $68 million for the nine months ended January 25, 2019 and January 26, 2018, respectively. Additionally, for the nine months ended January 26, 2018, other operating expense, net includes an $80 million contribution to the Medtronic Foundation. There were no contributions to the Medtronic Foundation during the nine months ended January 25, 2019. These benefits were partially offset by intangible asset impairments and other charges of $149 million associated with business exits during the nine months ended January 25, 2019 and a reduction of Transition Service Agreement income.

Other Non-Operating (Income) Expense, Net Other non-operating (income) expense, net includes the non-service component of net periodic pension and postretirement benefit cost, investment gains and losses, and interest income. For the three and nine months ended January 25, 2019, other non-operating (income) expense, net was income of $71 million and $309 million, respectively, as compared to expense of $139 million and income of $67 million for the three and nine months ended January 26, 2018, respectively. The change in other non-operating (income) expense, net for the three and nine months ended January 25, 2019, as compared to the corresponding periods in the prior fiscal year, was driven primarily by a loss of $227 million related to the impairment of certain cost and equity method investments in the three and nine months ended January 26, 2018. The change in other non-operating (income) expense, net during the three and nine months ended January 25, 2019 was also attributable to an increase in investment gains on our minority investment portfolio, partially due to the adoption of new accounting guidance in the first quarter of fiscal year 2019. These increases were partially offset by a decrease in interest income for the three and nine months ended January 25, 2019, as compared to the corresponding periods in the prior fiscal year. Refer to Note 2 to the current period's consolidated financial statements for more information on recently adopted accounting pronouncements.

Interest Expense Interest expense includes interest incurred on our outstanding borrowings, amortization of debt issuance costs and debt premiums or discounts, amortization of gains or losses on terminated or de-designated interest rate derivative instruments, and ineffectiveness on interest rate derivative instruments. For the three and nine months ended January 25, 2019, interest expense was $243 million and $726 million, respectively, as compared to $270 million and $829 million for the three and nine months ended January 26, 2018, respectively. The decrease in interest expense during the three and nine months ended January 25, 2019 was primarily driven by a decrease in total debt obligations, on average, compared to the corresponding periods in the prior fiscal year.

INCOME TAXES

	Three months ended		Nine months ended	
(in millions)	**January 25, 2019**	**January 26, 2018**	**January 25, 2019**	**January 26, 2018**
Income tax provision	$ 99	$ 2,419	$ 437	$ 2,320
Income before income taxes	1,370	1,027	3,905	3,950
Effective tax rate	7.2%	235.5 %	11.2%	58.7 %
Non-GAAP income tax provision	$ 272	$ 293	$ 773	$ 780
Non-GAAP income before income taxes	2,025	1,882	5,794	5,354
Non-GAAP Nominal Tax Rate	13.4%	15.6 %	13.3%	14.6 %
Difference between the effective tax rate and Non-GAAP Nominal Tax Rate	6.2%	(219.9)%	2.1%	(44.1)%

On December 22, 2017, the U.S. government enacted the Tax Act. U.S. GAAP requires that the impact of tax legislation be recognized in the period in which the law was enacted. The Company adopted guidance allowing for a measurement period, not to exceed one year, to finalize the accounting for the income tax impacts of the Tax Act. The measurement period closed during the three months ended January 25, 2019. Refer to Note 12 to the current period's consolidated financial statements for additional information.

Many of the countries we operate in have statutory tax rates lower than our U.S. statutory rate, thereby resulting in an overall effective tax rate less than the U.S. statutory rate of 21 percent. A significant portion of our earnings are generated from operations in Puerto Rico, Switzerland, and Ireland. The statutory tax rates for these jurisdictions range from 12.5 percent to 45.1 percent. Our earnings in Puerto Rico and Switzerland are subject to certain tax incentive grants which provide for tax rates lower than the country statutory tax rates. Unless our tax incentive grants are extended, they will expire between fiscal years 2019 and 2029. The tax incentive grants scheduled to expire during fiscal year 2019 are not

expected to have a material impact on our financial results. Refer to Note 14 to the consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended April 27, 2018 for additional information.

Our effective tax rate for the three and nine months ended January 25, 2019 was 7.2 percent and 11.2 percent, respectively, as compared to 235.5 percent and 58.7 percent for the three and nine months ended January 26, 2018, respectively. The decrease in our effective tax rate for the three and nine months ended January 25, 2019, as compared to the corresponding periods in the prior fiscal year, was primarily due to the impacts from U.S. tax reform. Further driving the decrease were the impacts from certain tax adjustments, the gain on the divestiture of our Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses during the second quarter of fiscal year 2018, the impact from investment losses, and operational tax adjustments described below, along with year-over-year changes in operational results by jurisdiction.

Our Non-GAAP Nominal Tax Rate for the three and nine months ended January 25, 2019 was 13.4 percent and 13.3 percent, respectively, as compared to 15.6 percent and 14.6 percent for the three and nine months ended January 26, 2018, respectively. The change in our Non-GAAP Nominal Tax Rate was primarily due to the finalization of certain tax returns and audits, the impact from the lapse of federal statutes of limitations, excess tax benefits related to stock-based compensation, and year-over-year changes in operational results by jurisdiction. An increase in our Non-GAAP Nominal Tax Rate of 1 percent would result in an additional income tax provision for the three and nine months ended January 25, 2019 of approximately $20 million and $58 million, respectively.

Certain Tax Adjustments

During the three months ended January 25, 2019, the net benefit from certain tax adjustments of $64 million, recognized in *income tax provision* in the consolidated statements of income, included the following:

- A net benefit of $12 million associated with the transition tax liability and the Tax Act impact to deferred tax assets, liabilities, and valuation allowances, as noted above.
- A benefit of $32 million related to intercompany legal entity restructuring.
- A net benefit of $20 million associated with the finalization of certain income tax aspects of the divestiture of our Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses.

During the nine months ended January 25, 2019, the net benefit from certain tax adjustments of $35 million, recognized in *income tax provision* in the consolidated statements of income, included the following:

- A net benefit of $25 million associated with the transition tax liability and the Tax Act impact to deferred tax assets, liabilities, and valuation allowances, as noted above.
- A $32 million benefit of related to intercompany legal entity restructuring.
- A $20 million net benefit associated with the finalization of certain income tax aspects of the divestiture of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses.
- A charge of $42 million related to the recognition of a prepaid tax expense resulting from the reduction in the U.S. statutory tax rate under the Tax Act and the current quarter sale of U.S. manufactured inventory held as of April 27, 2018.

During the three months ended January 26, 2018, the net charge from certain tax adjustments of $2.2 billion, recognized in *income tax provision* in the consolidated statements of income, included the following:

- A net charge of $2.2 billion associated with U.S. tax reform.

During the nine months ended January 26, 2018, the net charge from certain tax adjustments of $1.9 billion, recognized in *income tax provision* in the consolidated statements of income, included the following:

- A net charge of $2.2 billion associated with U.S. tax reform.
- A net benefit of $398 million associated with the intercompany sales of intellectual property.
- A net charge of $37 million primarily related to the sale of our Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses.

LIQUIDITY AND CAPITAL RESOURCES

Our liquidity and capital structure is evaluated regularly within the context of our annual operating and strategic planning process. We consider the liquidity necessary to fund our operations, which includes working capital needs, investments in research and development, property, plant, and equipment, and other operating costs. We also consider capital allocation alternatives that balance returning value to shareholders through dividends and share repurchases, satisfying maturing debt, and acquiring businesses and technology.

Summary of Cash Flows

The following is a summary of cash provided by (used in) operating, investing, and financing activities, the effect of exchange rate changes on cash and cash equivalents, and the net change in cash and cash equivalents:

	Nine months ended	
(in millions)	January 25, 2019	January 26, 2018
Cash provided by (used in):		
Operating activities	$ 4,920	$ 3,646
Investing activities	(245)	5,747
Financing activities	(4,571)	(8,126)
Effect of exchange rate changes on cash and cash equivalents	(70)	124
Net change in cash and cash equivalents	$ 34	$ 1,391

Operating Activities The $1.3 billion increase in net cash provided was primarily driven by our operating margin expansion and an increase in cash collected from customers, as well as decreases in cash paid to suppliers and other vendors, certain litigation payments, cash paid for interest, and retirement benefit plan contributions, partially offset by an increase in cash paid for taxes. The increase in cash collected from customers reflects collections on higher sales during the nine months ended January 25, 2019 as compared to the nine months ended January 26, 2018, and the decrease in cash paid to suppliers is primarily due to our continued progress in extending supplier payment terms. The decrease in certain litigation payments resulted from changes in the timing of payments across fiscal quarters. Cash paid for interest decreased primarily due to a decrease in total debt obligations. The decrease in retirement benefit plan contributions reflects lower contributions to the U.S. pension plan in fiscal year 2019 as compared to fiscal year 2018. The increase in cash paid for taxes is primarily due to our transition tax payment in the second quarter of fiscal year 2019.

Investing Activities The $6.0 billion decrease in net cash provided was primarily attributable to the sale of the Patient Care, Deep Vein Thrombosis, and Nutritional Insufficiency businesses during the nine months ended January 26, 2018, which resulted in net proceeds of $6.1 billion, and more cash paid for acquisitions during the nine months ended January 25, 2019, primarily due to the acquisition of Mazor Robotics in the third quarter of fiscal year 2019, partially offset by higher net sales of investments of $1.6 billion during the nine months ended January 25, 2019 as compared to the corresponding period in the prior fiscal year.

Financing Activities The $3.6 billion decrease in net cash used was primarily attributable to the repayment of our senior unsecured term loan, including accrued interest, for $3.0 billion and the repayment of our 6.000 percent ten-year 2008 CIFSA senior notes, including accrued interest, for $1.2 billion during the nine months ended January 26, 2018. The decrease in net cash used was also due to an increase in issuances of ordinary shares of $558 million, offset by higher share repurchases of $764 million and higher repayments of commercial paper borrowings of $301 million during the nine months ended January 25, 2019, as compared to the corresponding period in the prior fiscal year.

Free Cash Flow

Free cash flow, a non-GAAP financial measure, is calculated by subtracting additions to property, plant, and equipment from net cash provided by operating activities. Management uses this non-GAAP financial measure, in addition to U.S. GAAP financial measures, to evaluate our operating results. Free cash flow should be considered supplemental to, and not a substitute for, our reported financial results prepared in accordance with U.S. GAAP. Reconciliations between net cash provided by operating activities (the most comparable U.S. GAAP measure) and free cash flow are as follows:

	Nine months ended	
(in millions)	**January 25, 2019**	**January 26, 2018**
Net cash provided by operating activities	$ 4,920	$ 3,646
Net cash (used in) provided by investing activities	(245)	5,747
Net cash used in financing activities	(4,571)	(8,126)
Net cash provided by operating activities	$ 4,920	$ 3,646
Additions to property, plant, and equipment	(799)	(776)
Free cash flow	$ 4,121	$ 2,870
Dividends to shareholders	$ 2,022	$ 1,870
Repurchase of ordinary shares	2,728	1,964
Issuances of ordinary shares	(891)	(333)
Return to shareholders	$ 3,859	$ 3,501
Return of operating cash flow percentage	78%	96%
Return of free cash flow percentage	94%	122%

Debt and Capital

Our capital structure consists of equity and interest-bearing debt. We use a combination of bank borrowings and commercial paper issuances to fund our short-term financing needs. Current debt, including the current portion of our long-term debt and capital lease obligations, was $1.4 billion at January 25, 2019 as compared to $2.1 billion at April 27, 2018. Long-term debt was $23.7 billion at both January 25, 2019 and April 27, 2018. We utilize unsecured senior debt obligations to meet our long-term financing needs. From time to time, we may repurchase our outstanding debt obligations in the open market or through privately negotiated transactions.

Total debt at January 25, 2019 was $25.0 billion, as compared to $25.8 billion at April 27, 2018. The decrease in total debt was primarily driven by a reduction in our commercial paper borrowings of $698 million.

We maintain a commercial paper program for short-term financing, which allows us to issue unsecured commercial paper notes on a private placement basis up to a maximum aggregate amount outstanding at any time of $3.5 billion. At January 25, 2019, we had no commercial paper outstanding, as compared to $698 million at April 27, 2018. There was no commercial paper activity during the three months ended January 25, 2019. During the nine months ended January 25, 2019, the weighted average original maturity of the

commercial paper outstanding was approximately 28 days, and the weighted average interest rate was 2.10 percent. The issuance of commercial paper reduces the amount of credit available under our existing revolving credit facility, as explained below.

We also have a $3.5 billion five-year syndicated revolving credit facility (Credit Facility), which was amended and restated in December 2018, and now expires in December 2023. The Credit Facility provides backup funding for the commercial paper program and may also be used for general corporate purposes. At January 25, 2019 and April 27, 2018, no amounts were outstanding under the Credit Facility.

Interest rates on advances under the Credit Facility are determined based on our long-term debt ratings assigned by S&P and Moody's. For additional information on our credit ratings status by S&P and Moody's, refer to the "Liquidity" section of this Management's Discussion and Analysis. Facility fees are payable on the Credit Facility and are determined in the same manner as the interest rates. The agreement governing the Credit Facility also contains customary covenants, all of which we were in compliance with at January 25, 2019.

We repurchase shares from time to time as part of our focus on returning value to our shareholders. In June 2017, our Board of Directors authorized the expenditure of up to $5.0 billion for new share repurchases. During the three and nine months ended January 25, 2019, we repurchased a total of 7.3 million and 29.1 million shares, respectively, at an average price per share of $91.98 and $91.42, respectively. At January 25, 2019, we had approximately $1.3 billion remaining under the share repurchase program authorized by our Board of Directors.

On February 20, 2019, we announced the commencement of a cash tender offer for up to $5.0 billion of certain of our outstanding senior notes. The tender offer will expire on March 19, 2019 unless extended or terminated. The tender offer is subject to a number of conditions, including the condition that we receive net proceeds from one or more debt financings sufficient to fund the purchase of tendered notes.

For more information on credit arrangements, refer to Note 8 to the current period's consolidated financial statements, and Note 8 to the consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended April 27, 2018.

Liquidity

The following table is a summary of our cash, cash equivalents, and current investments, working capital, and current ratio:

(in millions)	January 25, 2019	April 27, 2018
Cash, cash equivalents, and current investments	$ 9,142	$ 11,227
Working capital	12,024	12,896
Current ratio	2.4:1.0	2.3:1.0

Our liquidity sources at January 25, 2019 include $3.7 billion of cash and cash equivalents and $5.4 billion of current investments. Additionally, we maintain a commercial paper program (no commercial paper outstanding at January 25, 2019) and Credit Facility. See discussion above regarding changes in our cash and cash equivalents and commercial paper program and Credit Facility.

Our current investments include marketable debt and equity securities. Our debt and equity securities include U.S. and non-U.S. government and agency securities, corporate debt securities, mortgage-backed securities, other asset-backed securities, equity securities, and auction rate securities. Some of our investments may experience reduced liquidity due to changes in market conditions

and investor demand. Our auction rate security holdings continue to experience reduced liquidity due to low investor demand. Although our auction rate securities are currently illiquid and other securities could become illiquid, we believe we could liquidate a substantial amount of our portfolio without incurring a material impairment loss.

For the three and nine months ended January 25, 2019, the total other-than-temporary impairment losses on available-for-sale debt securities were not significant. Based on our assessment of the credit quality of the underlying collateral and credit support available to each of the remaining securities in which we are invested, we believe we have recognized all necessary other-than-temporary impairments as we do not have the intent to sell, nor is it more likely than not that we will be required to sell, before recovery of the amortized cost. At January 25, 2019, we have $124 million of gross unrealized losses on our aggregate available-for-sale debt securities of $5.5 billion. If market conditions deteriorate, some of these holdings may experience other-than-temporary impairment in the future, which could adversely affect our financial results. We are required to use estimates and assumptions in our valuation of investments, which requires a high degree of judgment, and therefore, actual results could differ materially from estimates. Refer to Note 7 to the current period's consolidated financial statements for additional information regarding fair value measurements.

The tables below includes our short- and long-term debt ratings from Standard & Poor's Ratings Services and Moody's Investors Service at both January 25, 2019 and April 27, 2018:

	Agency Rating[1]	
	January 25, 2019	April 27, 2018
Standard & Poor's Ratings Services		
Long-term debt	A	A
Short-term debt	A-1	A-1
Moody's Investors Service		
Long-term debt	A3	A3
Short-term debt	P-2	P-2

(1) Agency ratings are subject to change, and there may be no assurance that an agency will continue to provide ratings and/or maintain its current ratings. A security rating is not a recommendation to buy, sell or hold securities, and may be subject to revision or withdrawal at any time by the rating agency, and each rating should be evaluated independently of any other rating.

Standard & Poor's Ratings Services (S&P) and Moody's Investors Service (Moody's) long-term debt ratings and short-term debt ratings at January 25, 2019 were unchanged as compared to the ratings at April 27, 2018. We do not expect the S&P and Moody's ratings to have a significant impact on our liquidity or future flexibility to access additional liquidity given our balance sheet and Credit Facility and related commercial paper program.

We have future contractual obligations and other minimum commercial commitments that are entered into in the normal course of business. We believe our off-balance sheet arrangements do not have a material current or anticipated future effect on our consolidated earnings, financial position, and/or cash flows. Refer to the "Off-Balance Sheet Arrangements and Long-Term Contractual Obligations" section of Management's Discussion and Analysis in our Annual Report on Form 10-K for the fiscal year ended April 27, 2018 for more information on these obligations and commitments.

Note 17 to the current period's consolidated financial statements provides information regarding amounts we have accrued related to legal matters. In accordance with U.S. GAAP, we record a liability in our consolidated financial statements for these matters when a loss is known or considered probable and the amount can be reasonably estimated. Actual settlements may be different than estimated and could have a material effect on our consolidated earnings, financial position, and/or cash flows.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

We record tax liabilities in our consolidated financial statements for amounts that we expect to repatriate from subsidiaries (to the extent the repatriation would be subject to tax); however, no tax liabilities are recorded for amounts that we consider to be permanently reinvested. We have removed our permanently reinvested assertion on earnings through April 27, 2018 for legal entities subject to the one-time repatriation tax. We expect to have access to the majority of our cash flows in the future. In addition, we continue to evaluate our legal entity structure supporting our business operations, and to the extent such evaluation results in a change to our overall business structure, we may be required to accrue for additional tax obligations.

We believe our balance sheet and liquidity provide us with flexibility in the future, and that our cash, cash equivalents, and short-term investments, as well as our Credit Facility and related commercial paper program, will satisfy our foreseeable operating needs for at least the next 12 months. We regularly review our capital needs and consider various investing and financing alternatives to support our requirements.

Off-Balance Sheet Arrangements and Long-Term Contractual Obligations

There have been no material changes to our off-balance sheet arrangements and long-term contractual obligations as reported in our most recent Annual Report filed on Form 10-K for the fiscal year ended April 27, 2018.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, and other written reports and oral statements made by or with the approval of one of the Company's executive officers from time to time, may include "forward-looking" statements. All statements other than statements of historical fact contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy and plans, objectives of management for future operations and current expectations or forecasts of future results, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. Our forward-looking statements may include statements related to our growth and growth strategies, developments in the markets for our products, therapies and services, financial results, product development launches and effectiveness, research and development strategy, regulatory approvals, competitive strengths, restructuring and cost-saving initiatives, intellectual property rights, litigation and tax matters, government investigations, mergers and acquisitions, divestitures, market acceptance of our products, therapies and services, accounting estimates, financing activities, ongoing contractual obligations, working capital adequacy, value of our investments, our effective tax rate, our expected returns to shareholders, and sales efforts. In some cases, such statements may be identified by the use of terminology such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "looking ahead," "may," "plan," "possible," "potential," "project," "should," "will," and similar words or expressions. Forward-looking statements in this Quarterly Report include, but are not limited to, statements regarding our ability to drive long-term shareholder value, development and future launches of products and continued or future acceptance of products, therapies and services in our segments; expected timing for completion of research studies relating to our products; market positioning and performance of our products, including stabilization of certain product markets; divestitures and the potential benefits thereof; the costs and benefits of integrating previous acquisitions; anticipated timing for U.S. FDA and non-U.S. regulatory approval of new products; increased presence in new markets, including markets outside the U.S.; changes in the market and our market share; acquisitions and investment initiatives, as well as integration of acquired companies into our operations; the resolution of tax matters; the effectiveness of our development activities in reducing patient care costs and hospital stay lengths; our approach towards cost containment; our expectations regarding health care costs, including potential changes to reimbursement policies and pricing pressures; our expectations regarding changes to patient standards of care; our ability to identify and maintain successful business partnerships; the elimination of certain positions or costs related to restructuring initiatives; outcomes in our litigation matters and government investigations; general economic conditions; the adequacy of available working capital and our working capital needs; our payment of dividends and redemption of shares; the continued strength of our balance sheet and liquidity; our accounts receivable exposure; and the potential impact of our compliance with governmental regulations and accounting guidance.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in the "Risk Factors" section and elsewhere in our Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. One must carefully consider forward-looking statements and understand that such forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, and involve a variety of risks and uncertainties, known and unknown, including, among others, those discussed in the sections entitled "Government Regulation and Other Considerations" within "Item 1. Business" and "Item 1A. Risk Factors" in our Annual Report on Form 10-K, as well as those related to:

- competition in the medical device industry;
- reduction or interruption in our supply;
- quality problems, liquidity shortfalls;
- decreasing prices and pricing pressure;
- fluctuations in currency exchange rates;
- changes in applicable tax rates;
- positions taken by taxing authorities;
- adverse regulatory action;

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

- delays in regulatory approvals;
- litigation results;
- self-insurance;

- commercial insurance;
- health care policy changes;
- international operations;
- cybersecurity incidents;
- failure to complete or achieve the intended benefits of acquisitions or divestitures; or
- disruption of our current plans and operations.

Consequently, no forward-looking statement may be guaranteed and actual results may vary materially from those projected in the forward-looking statements. We intend to take advantage of the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995 regarding our forward-looking statements, and are including this sentence for the express purpose of enabling us to use the protections of the safe harbor with respect to all forward-looking statements. While we may elect to update these forward-looking statements at some point in the future, whether as a result of any new information, future events, or otherwise, we have no current intention of doing so except to the extent required by applicable law.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

CURRENCY EXCHANGE RATE RISK

Due to the global nature of our operations, we are exposed to currency exchange rate changes which may cause fluctuations in earnings and cash flows. We use operational and economic hedges, as well as currency exchange rate derivative instruments, to manage the impact of currency exchange rate fluctuations. In order to minimize earnings and cash flow volatility resulting from currency exchange rate fluctuations, we enter into derivative instruments, principally forward currency exchange rate contracts. These contracts are designed to hedge anticipated transactions in other currencies and changes in the value of specific assets and liabilities. At inception of the contract, the derivative instrument is designated as either a freestanding derivative or a cash flow hedge. The primary currencies of our derivative instruments are the Euro, Japanese Yen, and British Pound. Fluctuations in the currency exchange rates of currency exposures that are unhedged, such as in certain emerging markets, may result in future earnings and cash flow volatility. We do not enter into currency exchange rate derivative instruments for speculative purposes.

The gross notional amount of all currency exchange rate derivative instruments outstanding at January 25, 2019 and April 27, 2018 was $12.2 billion and $11.5 billion, respectively. At January 25, 2019, these contracts were in a net unrealized gain position of $219 million. A sensitivity analysis of changes in the fair value of all currency exchange rate derivative contracts at January 25, 2019 indicates that, if the U.S. dollar uniformly strengthened/weakened by 10 percent against all currencies, the fair value of these contracts would increase/decrease by approximately $958 million. Any gains and losses on the fair value of derivative contracts would generally be offset by gains and losses on the underlying transactions. These offsetting gains and losses are not reflected in the above analysis.

In the second quarter of fiscal year 2019, we began accounting for our operations in Argentina as highly inflationary, as the prior three-year cumulative inflation rate exceeded 100 percent. The change did not have a material impact on our results for the three or nine months ended January 25, 2019.

INTEREST RATE RISK

We are subject to interest rate risk on our short-term investments and our borrowings. We manage interest rate risk in the aggregate, while focusing on our immediate and intermediate liquidity needs. Our debt portfolio at January 25, 2019 was comprised of debt predominately denominated in U.S. dollars, of which substantially all is fixed rate debt. We are also exposed to interest rate changes affecting our investments in interest rate sensitive instruments, which include our marketable debt securities, fixed-to-floating interest rate swap agreements, and forward starting interest rate swap agreements.

Document received on 5/6/19 5:24 PM Document accepted on 05/07/2019 08:38:06 # 4519414/170431220042

A sensitivity analysis of the impact on our interest rate-sensitive financial instruments of a hypothetical 10 basis point change in interest rates, compared to interest rates at January 25, 2019, indicates that the fair value of these instruments would correspondingly change by $94 million.

For a discussion of current market conditions and the impact on our financial condition and results of operations, please see the "Liquidity" section of the current period's Management's Discussion and Analysis. For additional discussion of market risk, refer to Notes 7 and 9 to the current period's consolidated financial statements.

Item 4. Controls and Procedures

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) and changes in the Company's internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) are effective.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

The Company is deploying an enterprise resource planning (ERP) software program, SAP, to the Minimally Invasive Therapies Group. During fiscal year 2019, the Company continued the deployment of this software along with other enterprise systems, which resulted in changes to the internal controls over financial reporting for the Minimally Invasive Therapies Group in Latin America. The internal controls were updated to reflect these changes. These system deployments will continue with projected completion in fiscal year 2020. There have been no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act) during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

A discussion of the Company's policies with respect to legal proceedings is included in the management's discussion and analysis, and our legal proceedings and other loss contingencies are described in Note 17 to the current period's consolidated financial statements.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Purchases of Equity Securities

The following table provides information about the shares repurchased by the Company during the third quarter of fiscal year 2019:

Fiscal Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as a Part of Publicly Announced Program [1]	Maximum Approximate Dollar Value of Shares that may yet be Purchased Under the Program [1]
10/27/2018 - 11/23/2018	3,284,100	$ 91.99	3,284,100	$ 1,694,007,364
11/24/2018 - 12/28/2018	2,931,430	94.31	2,931,430	1,417,530,516
12/29/2018 - 1/25/2019	1,097,502	85.68	1,097,502	1,323,491,730
Total	7,313,032	$ 91.98	7,313,032	$ 1,323,491,730

(1) In June 2017, the Company's Board of Directors authorized the repurchase of $5 billion of the Company's ordinary shares. There is no specific time-period associated with this repurchase authorization.

Item 6. Exhibits

(a) Exhibits

10.1	Amended and Restated Credit Agreement (incorporated by reference to Exhibit 10.1 to Medtronic plc's Current Report on Form 8-K filed with the Commission on December 12, 2018)
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Schema Document.
101.CAL	XBRL Calculation Linkbase Document.
101.DEF	XBRL Definition Linkbase Document.
101.LAB	XBRL Label Linkbase Document.
101.PRE	XBRL Presentation Linkbase Document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MEDTRONIC PUBLIC LIMITED COMPANY
(Registrant)

Date: March 1, 2019

/s/ Omar Ishrak
Omar Ishrak
Chairman and Chief Executive Officer

Date: March 1, 2019

/s/ Karen L. Parkhill
Karen L. Parkhill
Executive Vice President and
Chief Financial Officer

EXHIBIT Q

smiths medical
bringing technology to life

Smiths Medical
6000 Nathan Lane N
Minneapolis, MN 55442
T: 763 383 3000
F: 763 383 3679
www.smiths-medical.com

February 22, 2019

Dear Bivona® Customer,

Smiths Medical is experiencing a supply disruption on our Bivona® tracheostomy tubes portfolio due to the Environmental Protection Agency shutdown of the Sterigenics sterilization site in Willowbrook, IL. All product codes in the *standard* Bivona® family are impacted by this shutdown. Our team is working diligently with Sterigenics to determine alternatives for sterilization of these critical products and we will notify you as soon as sterilization resumes.

Smiths Medical non-sterilized Bivona® tubes from our custom lab are not impacted by this disruption.

We value your business and appreciate your understanding during this challenging time, and recognize providing a tracheostomy tube to your patient is the most important objective.

If you have any questions, please contact your local Smiths Medical representative, or contact our customer service team at 1-800-250-5361.

Respectfully,

Joan Cummings
Marketing Director
Smiths Medical

EXHIBIT R

U.S. FOOD & DRUG ADMINISTRATION

CDRH Message: Medical Devices Supply Issue and Potential Shortages as Sterigenics Willowbrook Product Sterilization Facility Ceases Operations

Supply issues can lead to shortages of medical devices—and can pose a threat to public health by delaying or disrupting critical care for patients. Mitigating product supply issues and working to prevent patient harm from device shortages are important to the U.S. Food and Drug Administration (FDA).

The FDA's Center for Devices and Radiological Health (CDRH) is aware that on February 15, 2019, the Illinois Environmental Protection Agency (EPA) issued a Seal Order to stop the Sterigenics facility in Willowbrook, Illinois, from sterilizing medical products and other products with ethylene oxide. Learn more about the Environmental Protection Agency's assessment of Sterigenics Willowbrook Facility on EPA.gov.

Medical devices account for over 90 percent of the products that the Sterigenics Willowbrook facility sterilizes. The FDA is reaching out to medical device manufacturers to understand which manufacturers are affected by the cessation of operations at this sterilization facility. At this time, the FDA believes that more than 100 manufacturers and hundreds of devices may be affected.

Currently, the FDA is not aware of any device shortages. In case of a potential shortage, the FDA identifies strategies that will limit or mitigate patient impact due to device supply interruptions. The FDA also reaches out to device manufacturers who might not be affected by an issue to determine their availability to ramp up production and potentially mitigate a shortage.

Report Sterilization Site Changes to the FDA

- **Premarket Approval (PMA) Holders:** If you are a PMA holder affected by the cessation of operations at the Sterigenic's Willowbrook facility and you are planning to use an alternative facility to sterilize your products, you should submit a 180-day site change supplement. However, the FDA intends to review such PMA supplements within 30 days. The FDA recently issued the final guidance, Manufacturing Site Change Supplements: Content and Submission, that PMA holders can refer to for more information about site change supplements. If you have questions about your PMA device or need help with submitting a site change supplement, contact CDRHPremarketProgramOperations@fda.hhs.gov.
- **510(k) Holders:** If you are a 510(k) holder affected by the Sterigenic's Willowbrook

facility shutdown and you are planning to use an alternative ethylene oxide sterilization facility, submitting a new 510(k) is typically not required. You should document qualification activities supporting this change in your internal files. However, the FDA recommends that affected 510(k) holders refer to the FDA's guidance, Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff when determining if a new 510(k) is required.

Report a Medical Product Supply Issue or Shortage

Planning for and preventing device supply shortages is an important responsibility. The FDA can help anticipate, prevent or mitigate future shortages by working with device manufacturers that voluntarily provide us with information on potential product supply issues. Learn more about how to report a medical product shortage or supply issue.

Questions?

If you have questions about medical device supply issues or shortages, contact Deviceshortages@fda.hhs.gov.

U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

EXHIBIT S

De : MDB Enquiries / Enquêtes BMM (HC/SC) [mailto:hc.mdb.enquiries-enquetes.bmm.sc@canada.ca]
Envoyé : 5 mars 2019 18:13
À : Direction
Objet : Re: Shutdown of Sterigenics Sterilization Facility in Willowbrook, Illinois, US / Re: Fermeture du centre de stérilisation Sterigenics de Willowbrook, Illinois, É.-U. - CompanyID: 120417

(Le français suit ...)

March 5, 2019
Health Canada has recently become aware that Sterigenics U.S., LLC, a US contract sterilizer that provides ethylene oxide sterilization services to medical device manufacturers, received a Seal Order from the Illinois Environmental Protection Agency. The Seal Order requires Sterigenics to stop the sterilization facility in Willowbrook, Illinois, USA, from sterilizing medical devices with ethylene oxide.

Health Canada is reaching out to all medical device manufacturers to understand which manufacturers are affected by Sterigenics' shutdown, and to identify potential impacts on the continued availability of their products.

If you are a manufacturer of Class I – IV devices that is affected by the shutdown of the Sterigenics' Willowbrook facility, please identify yourself to Health Canada's Regulatory Operations and

th

Enforcement Branch **by Thursday, March 7 , 2019**, at hc.mdcu-ucim.sc@canada.ca. Please include "Sterigenics" in the email subject line to ensure its priority for review.

In your email, please provide information regarding your specific challenges related to this issue and indicate, as necessary, if you are seeking support for the development of strategies to mitigate or prevent any device shortages that may have a critical impact on patient care.

Reminder – Significant Changes

Health Canada is reminding manufacturers of Class II-IV medical devices that significant changes require pre-market approval from Health Canada. If you are considering alternative contract sterilizers, you will need to assess whether or not the change in facility would be considered a significant change requiring pre-market approval. When there are no changes to the device, device packaging, and method of sterilization, a change in the facility alone would not be considered a significant change and, therefore, would not require pre-market approval. A change in facility alone should, however, be communicated to Health Canada as part of your annual licence renewal report. For further information on significant change, refer to the following link for Health Canada's Guidance on the Interpretation of Significant Change of a Medical Device:

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-interpretation-significant-change-medical-device.html#a27

Questions or concerns regarding this communication should be directed to:

Medical Devices Bureau
Health Canada
Holland Cross Tower A
11 Holland Avenue Suite 511
AL 3005B
Ottawa ON K1A 0K9
CANADA
Phone: 613-957-4786
Email: hc.mdb.enquiries-enquetes.bmm.sc@canada.ca

David Boudreau, ing. Anik Michelle Chartrand, MSc, MBA

Executive Director
Medical Devices Bureau
Therapeutic Products Directorate
Health Products and Food Branch
Health Canada

Director
Medical Devices Compliance Program
Medical Devices and Clinical Compliance Directorate
Regulatory Operations and Enforcement Branch
Health Canada

Le 5 mars 2019

Santé Canada a récemment été avisé que *Sterigenics* U.S., SARL, un centre de stérilisation à contrat fournissant un service de stérilisation à l'oxyde d'éthylène aux fabricants de matériels médicaux, a reçu une ordonnance de fermeture de la part de la *Illinois Environmental Protection Agency*. L'ordonnance de fermeture exige que *Sterigenics* cesse la stérilisation à l'oxyde d'éthylène des matériels médicaux au centre de stérilisation de Willowbrook, Illinois, É.-U.

Santé Canada contacte tous les fabricants de matériels médicaux afin de savoir quels fabricants sont affectés par la fermeture du centre de *Sterigenics* et afin de cerner les répercussions possibles sur la disponibilité continue de leurs produits.

Si vous êtes fabricants d'instruments de classes I à IV et que vous êtes affectés par la fermeture du centre de Willowbrook de *Sterigenics*, veuillez vous identifier auprès de la Direction générale des opérations réglementaires et des régions de Santé Canada avant **jeudi le 7 mars 2019** au hc.mdcu-ucim.sc@canada.ca. Veuillez inscrire « Sterigenics » dans l'objet du courriel afin d'en assurer la priorité.

Dans votre courriel, veuillez fournir de l'information en ce qui concerne les enjeux spécifiques en lien avec ce problème et veuillez indiquer, au besoin, si vous cherchez du soutien quant au développement de stratégies afin de réduire ou d'éviter les pénuries de matériels et d'instruments qui pourraient avoir un impact important sur les soins aux patients.

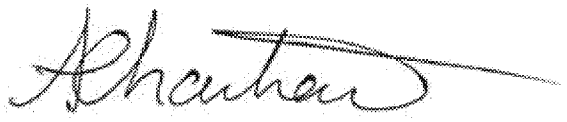
Rappel – Modifications importantes

Santé Canada tient à rappeler les fabricants d'instruments de classes II à IV que les modifications importantes exigent une approbation de Santé Canada précédant la mise en marché. Si vous envisagez faire appel à d'autres centres de stérilisation à contrat, vous devrez évaluer si le changement de centre est une modification assez importante nécessitant une approbation précédant la mise en marché. S'il n'y a pas de modifications quant à l'instrument, à l'emballage de l'instrument, ou à la méthode de stérilisation, un changement de centre de stérilisation à lui seul n'est pas considéré une modification assez importante et ne nécessite donc pas une approbation précédant la mise en marché. Un changement de centre de stérilisation devrait pourtant être transmis à Santé Canada dans le rapport du renouvellement annuel de l'homologation d'un matériel médical. Pour de plus amples informations sur les modifications importantes, veuillez consulter le lien suivant sur la Directive sur l'interprétation d'une modification importante d'un instrument médical de Santé Canada :

https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/instruments-medicaux/information-demandes/lignes-directrices/ligne-directrice-interpretation-modification-importante-instrument-medical.html#a27

Toutes questions ou préoccupations concernant le présent communiqué devraient être adressées au :

Bureau des matériels médicaux
Santé Canada
Holland Cross Tour A
11 Avenue Holland Suite 511
AL 3005B
Ottawa ON K1A 0K9
CANADA
Téléphone : 613-957-4786
Courriel : hc.mdb.enquiries-enquetes.bmm.sc@canada.ca



David Boudreau, ing.
Directeur exécutif
Bureau des matériels médicaux
Direction des produits thérapeutiques
Direction générale des produits de santé et des aliments
Santé Canada

Anik Michelle Chartrand, MSc, MBA
Directrice
Programme sur la conformité des instruments médicaux
Direction de la conformité des matériels médicaux et en milieux cliniques
Direction générale des opérations réglementaires et des régions
Santé Canada

EXHIBIT T

Illinois Health and Hospital Association

March 28, 2019

ILLINOIS HEALTH AND HOSPITAL ASSOCIATION
M E M O R A N D U M

TO: Deputy Governor Christian Mitchell
Illinois House Speaker Michael Madigan
Illinois House Republican Leader Jim Durkin
Illinois Senate President John Cullerton
Illinois Senate Republican Leader Bill Brady

Cc: Legislative Staff

FROM: A.J. Wilhelmi, President & CEO
David Gross, Senior Vice President, Government Relations

SUBJECT: **Potential Impact of Banning Ethylene Oxide (EtO) on Access to Healthcare**

On behalf of its over 200 hospital and nearly 50 health system members, the Illinois Health and Hospital Association (IHA) appreciates the opportunity to provide input on the work that the Administration and General Assembly are doing around the important issue of EtO. The hospital community recognizes that reasonable environmental oversight is necessary to protect the environment and the public from materials that may jeopardize health and safety. We rely on experts in environmental science to provide guidance and regulation to protect the public health. At the same time, patients' access to safe and effective health care will be affected if access to sterile medical supplies is disrupted. Thus, public policy must strike a careful balance between the appropriate regulation of EtO and patients' access to sterile medical supplies.

Banning Ethylene Oxide
Much of the discussion and legislative proposals set forth to date would completely phase out the use of EtO in Illinois over a defined period of time. We understand that there is significant concern about the health of communities where large EtO sterilization facilities are located. **However, there is serious concern that banning EtO will disrupt access to sterile medical supplies, and therefore, access to healthcare.** The following is the basis for our concerns:

Hospital Reliance on Illinois Based EtO Sterilizer
Medline is a key supplier of surgical and supply kits to many Illinois hospitals. If Medline's Lake County facility were to be impacted, there is significant concern regarding a potential disruption in access to medical and surgical supplies. Based on comments from Medline representatives, we understand that in addition to the Medline product, more than 20 medical device manufacturers utilize Medline's sterilization facility. Many of the devices that are sterilized at Medline's facility do not have access to backup sources to EtO sterilization. These devices will almost certainly be in shortage for many months if Medline's Lake County facility were to be impacted. **Nearly 80 percent of hospitals in Illinois utilize devices sterilized at Medline's Lake County facility.**[1]

[1] Based on statements from representatives of Medline.

1151 East Warrenville Rd.
P.O. Box 3015
Naperville, IL 60566
630.276.5400

700 South 2nd St.
Springfield, IL 62704
217.541.1150

400 North Capitol St. N.W.
Suite 585
Washington, DC 20001
202.624.7899

833 West Jackson Blvd.
Suite 610
Chicago, IL 60607
312.906.6150

www.team-iha.org

Hospitals Use of Pre-Sterilized Equipment and Supplies
For most surgeries and procedures, hospitals utilize pre-sterilized supply kits that include everything necessary for the procedure (e.g., bandages, gauze, gowns, drapes, surgical tubing and all other disposable materials used during surgery) as well as similar kits for labor and delivery. Many of these supply kits are customized based on the particular procedure or the requirements of the particular physician. Therefore, it would likely take hospitals several months to identify and switch to an alternative supplier, if available.

Concerns Raised by the U.S. Food and Drug Administration (FDA)
EtO is currently used to sterilize the supply and surgical kits discussed above. According to a March 26, 2019, Statement from the FDA, **"About half of all sterilized medical devices undergo sterilization using ethylene oxide."** While many sterilization methods are used (e.g., gamma radiation, e-beam, dry heat and steam sterilization), some sterilization methods are not compatible with some devices, components and materials.[2] The statement also recognizes the potential for a shortage of medical supplies: "[W]hile every effort is being taken to prevent a potential shortage, we're monitoring the situation closely and stand ready to act quickly with strategies intended to limit the impact of device supply interruptions on patients."

Finally, the FDA points out it will take time to develop new sterilization processes: "[A]s we continue to monitor any shortages associated with facility closings, we're also working with stakeholders … to identify innovative ways to sterilize medical devices that don't raise the same concerns as those identified at the Willowbrook facility. … We've already started exploring ways we can continue to ensure sterilization processes are safe and effective, and evolving with the current science. … We're seeking to not only limit the immediate impact of these facility closures, but also to identify new and improved methods for medical device sterilization."

For these reasons, there is significant concern that banning EtO will disrupt access to sterile medical supplies and healthcare for Illinois patients. IHA again appreciates the opportunity to provide input on this important issue. The use of EtO and its impact is very complex. The hospital community seeks to continue to work with you on this topic to ensure that environmental concerns are addressed while still allowing an avenue for hospitals to have access to appropriately sterilized medical products and equipment.

If you would like to discuss this issue further, please contact David Gross at 217-541-1161 or dgross@team-iha.org.

[2] US Food and Drug Administration (FDA), *Ethylene Oxide Sterilization for Medical Devices*

EXHIBIT U

TOM EMMER
8TH DISTRICT, MINNESOTA

COMMITTEES
FINANCIAL SERVICES
SUBCOMMITTEES
CAPITAL MARKETS AND GOVERNMENT SPONSORED ENTERPRISES
MONETARY POLICY AND TRADE
TERRORISM AND ILLICIT FINANCE

Congress of the United States
House of Representatives
Washington, DC 20515–2306

315 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-2331

DISTRICT OFFICE
9201 QUADDY AVENUE NE
SUITE 206
OTSEGO, MN 55330
(763) 241-6848

HOUSE REPUBLICAN STEERING

REPUBLICAN WHIP TEAM

DEPUTY WHIP TEAM

March 5, 2019

Dr. Scott Gottlieb
Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb:

We're writing to you regarding a timely and important issue facing medical device manufacturers located in Minnesota and throughout the country.

Last week, a key source of sterilization for many manufacturers was abruptly shut down by state-level environmental authorities due to environmental concerns. These concerns are very alarming and should continue to be addressed with a focus on the health and well-being of the residents in the immediate area. The sudden and unanticipated closing of this facility, however, is posing significant challenges to the supply of life-saving medical devices for patients.

The now-shuttered sterilization source was a preferred site for medical device manufacturers of all sizes, due to its large and significant medical device work and its known compliance to FDA and European Union standards. The loss of this site is particularly acute for small and medium sized manufacturers. Due to their smaller production volumes, this site was their only qualified and validated sterilization source.

The process to change the source of sterilization is complex and typically takes anywhere from three to six months to complete. Since this site shut-down was unexpected, manufacturers have as little as one or two months of supply ready and available. Without prompt action, patients could soon be facing a shortage of life-saving and quality of life improving medical devices.

Patients should not have to suffer for a mistake they had no part in making. We are asking you to immediately take any and all action needed to prevent this potentially tragic scenario, while continuing to ensure the safety and effectiveness of these devices. By acting swiftly, you can provide certainty to patients throughout the country that there will be no interruption to the supply of medical devices they need. Health care and industry experts across the country and throughout Minnesota's medical alley stand ready and willing to work with you and your agency to design a solution that accomplishes this.

Thank you for your consideration.

Sincerely,

Congress of the United States
Washington, DC 20515

Tom Emmer
Member of Congress

Dean Phillips
Member of Congress

Angie Craig
Member of Congress

Jim Hagedorn
Member of Congress

Betty McCollum
Member of Congress

Ilhan Omar
Member of Congress

Collin C. Peterson
Member of Congress

Peter Stauber
Member of Congress

EXHIBIT V

FDA STATEMENT

Statement from Jeff Shuren, M.D., director of the Center for Devices and Radiological Health, on agency efforts to mitigate temporary shortage of pediatric breathing tubes due to recent closure of Illinois sterilization facility

For Immediate Release:

April 12, 2019

Statement From:

Director - CDRH Offices: Office of the Center Director
Dr. Jeffrey E. Shuren MD JD

As part of the agency's ongoing efforts to minimize impacts of medical product shortages, last month, the FDA alerted (Statement from FDA Commissioner Scott Gottlieb, M.D., on steps the Agency is taking to prevent potential medical device shortages and ensure safe and effective sterilization amid shutdown of a large contract sterilization facility) the public of the potential for medical device shortages to arise from the closure of a large ethylene oxide sterilization facility in Willowbrook, Illinois, and the future planned closure of a similar facility in Michigan. Since the closure was announced, we have been taking steps to prevent patient harm from potential device shortages that could delay or disrupt critical care, including working to quickly and proactively secure alternative locations and methods for the sterilization of devices that were previously processed at the Willowbrook facility. We also committed to sharing updates on potential impacts to medical devices once sterilized at these facilities.

Despite best efforts to minimize the impact of the closures wherever possible, we have identified a medical device that is now in temporary shortage. Today, we are alerting health care professionals, parents and caregivers that there is a temporary shortage of a type of a tracheostomy tube manufactured by Smiths Medical. I want to assure you that the FDA is working closely with the company to quickly resolve their sterilization challenges and bring these critical devices to the patients who need them as quickly as possible, which we anticipate will be made available again beginning the week of April 22.

Smiths Medical's Bivona tracheostomy tubes (https://www.accessdata.fda.gov/cdrh_docs/pdf8/K083641.pdf) are used in health care facilities, such as hospitals, or at home to help adult and pediatric patients breathe. A tracheostomy is a surgical procedure that creates a small opening that goes through the skin and tissue of the neck directly into the windpipe (trachea). The tracheostomy tube is placed through this opening, called a stoma, into the trachea to allow a patient to breathe through the tube instead of through their mouth or nose. Prior to initial use, Bivona tracheostomy tubes are sterilized with ethylene oxide before they are marketed in the U.S. After initial use, patients may reuse the tubes by reprocessing them as described in Bivona's Instructions for Use (https://m.smiths-medical.com/~/media/M/Smiths-medical_com/Files/Import Files/TR194404GB-052015_LR.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). Hospitals also may clean the tubes and sterilize them so they can be reused on the same patient.

Although the Bivona tubes are indicated for use in both adult and pediatric patients, the temporary shortage is more likely to impact pediatric patients because supply of alternative tubes with similar functionality is limited. The Bivona tube is made from a flexible silicone material which makes them easier to insert in the stoma of pediatric patients. While there are other FDA-cleared silicone tracheostomy tubes for pediatric patients, there may not be enough available to adequately cover the shortage. We recognize the challenges this shortage imposes for these pediatric patients who need access to new tubes now, and are working to limit the impact to patients as much as possible by helping the company quickly move their sterilization to another facility.

During the temporary shortage, health care professionals who have patients urgently in need of a new Bivona tube should contact Smiths Medical directly to inquire about current inventory. Parents and caregivers who need new Bivona tubes (e.g., due to damage or leaking of current tubes) should work with their health care professionals to find an appropriate alternative until the Bivona tracheostomy tube is back on the market. Adult patients experiencing problems obtaining Bivona tubes should talk with their health care professional about using other FDA-cleared tracheostomy tubes, including those made from different materials.

The closure of the Willowbrook facility does not impact tubes already in use by patients at home or in health care settings. The company is communicating with patients about the tubes and how patients and caregivers can mitigate any potential impact, including re-using and cleaning tubes in accordance with the manufacturer's instructions for use.

The company is continuing to manufacture tracheostomy tubes per their normal schedule. The company has already started to use an alternative facility to sterilize their devices and estimates that approximately 28,000 new Bivona tracheostomy tubes are currently awaiting sterilization.

We are working closely with Smiths Medical to expedite release of sterilized tubes that still meet the FDA's standards for safety and effectiveness and expect new tubes to be available within the next few weeks.

At this time, we are not aware of any other shortages due to these closures. As with the case of Smiths Medical, early awareness and engagement enables us to be proactive and develop a plan to mitigate effects on patient care. We continue to monitor the situation closely, including any submissions to the FDA device shortages mailbox (mailto:deviceshortages@fda.hhs.gov) and stand ready to act quickly with strategies intended to limit the impact of device supply interruptions on patients. We are continuing to update our ethylene oxide in medical device sterilization (Ethylene Oxide Sterilization for Medical Devices) web page to ensure patients, health care professionals and industry have the most up-to-date information. As we previously noted, we're seeking to not only limit the immediate impact of these facility closures, but also to identify new and improved methods for medical device sterilization for which we will make additional announcements in the coming weeks.

We recognize the very real consequences that medical device shortages have on patients, and we'll continue to work directly with manufacturers, contract sterilizers, government agencies and other public health stakeholders to do all we can to avert new device shortages.

###

Inquiries

Media:

Alison Hunt (mailto:Alison.Hunt@fda.hhs.gov)

240-402-0764

Consumer:

888-INFO-FDA

Related Information

- FDA: Ethylene Oxide Sterilization for Medical Devices (/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices)
- FDA: Steps FDA is taking to prevent potential medical device shortages and ensure safe and effective sterilization amid shutdown of a large contract sterilization facility (Statement from FDA Commissioner Scott Gottlieb, M.D., on steps the Agency is taking to

prevent potential medical device shortages and ensure safe and effective sterilization amid shutdown of a large contract sterilization facility)

More Press Announcements (/news-events/newsroom/press-announcements)

EXHIBIT W

Cardinal Health
Woman and Baby
7200 Cardinal Place
Dublin, OH 43017

cardinalhealth.com

March 14, 2019

Dear Valued Customer:

We wanted to make you aware of a temporary supply disruption affecting the Kendall™ ACCU-TRACE Intrauterine Pressure Catheter (IUPC). We are currently working to resolve the issue, but this product will not be available until early August.

Material ID	Description
56300	Kendall™ ACCU-TRACE Intrauterine Pressure Catheter

Please work with your Cardinal Health™ representative to identify an alternate supplier who can offer a substitute in the interim.

We apologize for any inconvenience this may have caused. If you have further questions, please contact your Cardinal Health sales representative or Customer Service team at 800.964.5227.

Sincerely,

Kristin Harper
Global Vice President
Woman and Baby

EXHIBIT X

Guerbet

March 12, 2019

Guerbet LLC
821 Alexander Rd - Suite 204
Princeton, NJ 08540
Tel: 812-333-0059
Fax: 609-919-0495
www.guerbet-us.com

Dear Valued Guerbet Customer,

A major sterilization firm is experiencing an ongoing interruption in service. This impacts Guerbet as well as many other Medical Device and Pharmaceutical companies. LF branded consumables for Optistar®, Optivantage®, and Illumena® power injectors may experience limited availability until the interruption is resolved.

Guerbet is committed to resolving this interruption as quickly as possible while ensuring that any solution or change implemented provides the same level of sterility assurance and conformance to quality specifications as does the current process.

We apologize for any challenges these supply shortages may cause. We will be reaching out to you to work on possible solutions.

Sincerely,

Massimo Carrara

Massimo Carrara
North America Commercial VP

United States
Environmental Protection
Agency

Office of Air Quality
Planning and Standards
Research Triangle Park, NC 27711

EPA-456/R-97-004
September 1997

Air

EPA

ETHYLENE OXIDE COMMERCIAL STERILIZATION AND FUMIGATION OPERATIONS NESHAP

IMPLEMENTATION DOCUMENT

ETHYLENE OXIDE COMMERCIAL STERILIZATION AND FUMIGATION OPERATIONS NESHAP IMPLEMENTATION DOCUMENT

Prepared for:

Program Review Group
Information Technology and Program Integration Division
Office of Air Quality Planning and Standards
U. S. Environmental Protection Agency
Research Triangle Park, NC 27711

Prepared by:

Midwest Research Institute
Crossroads Corporate Park, 5520 Dillard Road, Suite 100
Cary, North Carolina 27511

September 1997

Disclaimer

The information provided in this document is intended as supplemental information to the regulated community. In case of any discrepancy between information provided in this document and the codified National Emission Standards for Hazardous Air Pollutants for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O), information contained in the codified standards will apply.

Mention of trade names or commercial products is not intended to constitute endorsement or recommendation for use. Copies of this report are available through the library Services Office (MD-35), U. S. Environmental Protection Agency, Research Triangle Park, NC 27711, or from National Technical Services, 5285 Port Royal Road, Springfield, Virginia 22161

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER 1
INTRODUCTION

1.1 BACKGROUND

Under Section 112 of the Clean Air Act (CAA), the U. S. Environmental Protection Agency (EPA) is required to develop national emission standards for hazardous air pollutants (NESHAP) for source categories that have been identified as major sources of hazardous air pollutants (HAP). Section 112(b) of the CAA identifies ethylene oxide (EO) as a HAP because it is suspected to cause cancer in humans, is highly mutagenic and teratogenic, and has significant acute and subchronic exposure health effects. To meet the requirements of the CAA, EPA promulgated NESHAP for ethylene oxide commercial sterilization and fumigation operations in the December 6, 1994 *Federal Register* as subpart O of part 63 of the Code of Federal Regulations.

Under this NESHAP, the EPA has elected to regulate both major (i.e., sources that emit or have the potential to emit 10 tons per year or more of any HAP or 25 tons per year or more of any combination of HAP) and area sources (i.e., any HAP source that is not a major source) because of the high toxicity of EO. Therefore, consistent with section 112(d) of the CAA, existing and new major sources will control emissions to the level achievable by the maximum achievable control technology (MACT); existing and new area sources will control emissions using generally available control technology (GACT).

Commercial sterilization and fumigation sources using EO as a sterilant for heat and moisture sensitive products and as a fumigant to control microorganisms or insects are subject to the regulation. However, the regulation exempts EO sterilizers in hospitals. Products that are typically sterilized or fumigated with EO include medical equipment and supplies, pharmaceuticals, spices, books, museum artifacts, and cosmetics. Approximately 200 EO commercial sterilization and fumigation sources exist in the United States; approximately 150 of these sources are expected to be affected by the regulation. The EPA estimates that full compliance with the regulation will reduce the amount of EO released into the air by 1,100 tons.

1.2 PURPOSE OF DOCUMENT

Under sections 112(d) and 112(l) of the CAA, EPA provides guidance useful to EPA Regional Office and State and local agency personnel who will be responsible for implementing NESHAP. The purpose of this document is to provide these personnel with implementation materials to assist them in conducting complete and efficient inspections at ethylene oxide commercial sterilization and fumigation operations to determine compliance with the NESHAP.

1.3 ORGANIZATION

Chapter 2 of this document presents a summary of the requirements of the regulation. Strategies for determining applicability of the regulation, including flowcharts, are provided in Chapter 3. Chapter 4 discusses the emission reductions and limits in the regulation and the control techniques that may be used to meet these standards. Requirements for demonstrating compliance with the regulation are discussed in Chapter 5. Chapter 6 summarizes the recordkeeping and reporting requirements of the regulation. Chapter 7 covers inspection procedures, including inspector checklists. A summary of commonly asked questions and answers are included in Chapter 8, and a list of other available implementation materials is included in Chapter 9. Appendix A contains a glossary of terms and nomenclature used in the regulation. A detailed "table of contents" of the regulation is included as Appendix B. A list of known facilities is included as Appendix C.

CHAPTER 2
SUMMARY OF THE REGULATION

The regulation affects sources using EO for commercial sterilization or fumigation operations. How a source is affected depends on the amount of EO that the source uses. In general, the regulation specifies:

- ✓ Compliance dates
- ✓ Emission reductions and limits
- ✓ Initial performance testing
- ✓ Ongoing monitoring
- ✓ Recordkeeping
- ✓ Reporting

Each of these requirements is summarized below. These requirements are discussed in more detail in subsequent chapters of this document. In addition, a detailed "table of contents" of the regulation is included in Appendix B of this document. It lists the requirements of the regulation and provides a cross-reference to the codified sections of the regulation where these requirements are found.

2.1 COMPLIANCE DATES[1]

All existing sources (i.e., initial startup date before December 8, 1997) that are subject to emissions standards (see section 2.2 below) must be in compliance with the regulation by December 6, 1997. All new sources (i.e., initial startup date after December 8, 1997) that are subject to emission standards must be in compliance with the regulation upon initial startup of the source.

[1]As of the publication date of this implementation document, the U. S. EPA is considering an extension of the compliance dates for these NESHAP. Readers are encouraged to consult future *Federal Register* notices for the latest compliance date information.

2.2 EMISSIONS REDUCTIONS AND LIMITS

The regulation specifies the following emission reductions and limits that depend on the piece of equipment and the amount of EO that the facility uses per year:

- ✓ For sterilization chamber vents (SCV's), at sources using 1 or more ton of EO per year, 99 percent reduction;
- ✓ For aeration room vents (ARV's) at sources using 10 or more tons of EO per year, 99 percent reduction OR 1 part per million by volume (ppmv) concentration limit; and
- ✓ For chamber exhaust vents (CEV's)/back draft vents at sources using 10 or more tons of EO per year, manifold to emission reduction device used to control SCV or ARV OR 99 percent reduction; for CEV's/back draft vents at sources using 1 to 10 tons of EO per year, 5,300 ppmv chamber concentration limit prior to activation of chamber exhaust.

2.3 INITIAL PERFORMANCE TESTING

Initial performance testing is required to demonstrate that the source is meeting the emissions standards. This is a one-time test. The regulation contains the test methods that will be used to determine initial compliance. During this initial performance test, the source will also establish operating parameter values that will be the bases for demonstrating ongoing compliance through monitoring of these parameters.

2.4 ONGOING MONITORING

Compliance with the regulation is demonstrated through ongoing monitoring of the operating parameter values established during initial testing. The monitoring requirements vary depending on the type of emission reduction technique the source uses. If using an acid-water scrubber, the source must monitor the ethylene glycol concentration or the scrubber liquor tank level once per week. If using a catalytic or thermal oxidation unit, the source must monitor the temperature continuously. For any type of emission reduction technique used to control emissions for ARV and for CEV (1 to 10 tons), the source may monitor the EO concentration once per hour for ARV and before activating the chamber exhaust for CEV.

2.5 RECORDKEEPING

The regulation requires that all sources keep records to document compliance with the regulation. Records for sources using 1 ton or more of EO per year include performance test results, monitoring and calibration data, and malfunctions and exceedances data. Records for sources using less than 1 ton of EO per year include annual usage data to demonstrate that they are not subject to the emission reduction requirements.

2.6 REPORTING

Reports for sources using 1 or more tons the EO per year include initial notification that the source is subject to the regulation, notification of performance tests and monitoring system evaluations, initial statement of compliance, and semi-annual compliance reports (on-going) containing information on the compliance status of the source.

CHAPTER 3
APPLICABILITY OF THE REGULATION

3.1 APPLICABILITY

The regulation applies to virtually all commercial sterilization and fumigation sources that use EO as a sterilant for heat and moisture sensitive products or as a fumigant to control microorganisms or insects, regardless of size (see exemptions listed in section 3.2). Both major and area sources are covered by the regulation. (Major sources are sources emitting 10 or more tons per year of any HAP or 25 or more tons per year of any combination of HAP's. Area sources, also referred to as "nonmajor sources," are sources that do not qualify as major.) The flowcharts in Figures 3-1 and 3-2 may be used to determine applicability of the requirements of the regulation to a particular source. Figure 3-1 highlights the requirements for sources using 1 to 10 tons of EO per year; Figure 3-2 highlights the requirements for sources using 10 tons or more of EO per year.

3.2 EXEMPTIONS

The regulation specifically exempts certain types of sources. These sources are:

- ✓ Beehive fumigators;
- ✓ Research and laboratory facilities, as defined in section 112(c)(7) of the CAA; and
- ✓ Medical facilities such as hospitals, doctors offices, clinics, or other facilities whose primary purpose is providing medical services to humans or animals.

3.3 SOURCE DESCRIPTION

The commercial sterilization source category covers the use of EO as a sterilant/fumigant in the production of medical equipment supplies and in miscellaneous sterilization and fumigation operations. Commercial sterilization facilities use EO as a sterilant for heat- or moisture-sensitive materials or as a fumigant to control microorganisms or insects. A variety of materials are sterilized or fumigated with EO, including medical equipment (e.g., syringes and surgical gloves), spices, cosmetics, and pharmaceuticals. Libraries and museums use EO to fumigate books and other historical items.

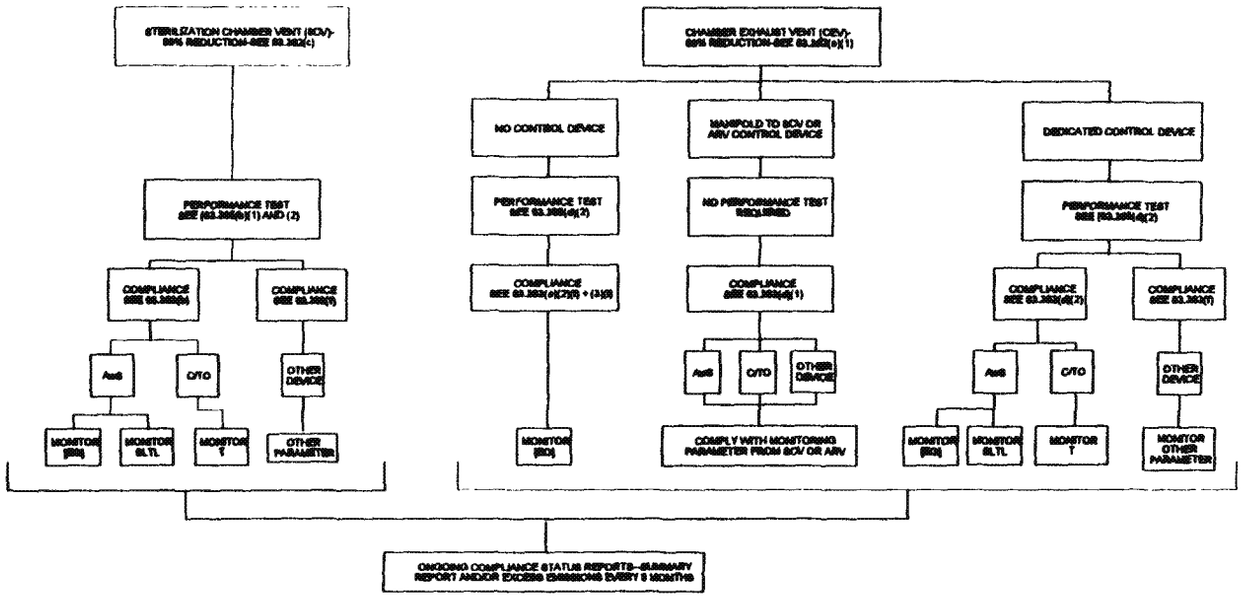


Figure 3-1. Applicability flowchart for sources using 1 to 10 tons of ethylene oxide per year.

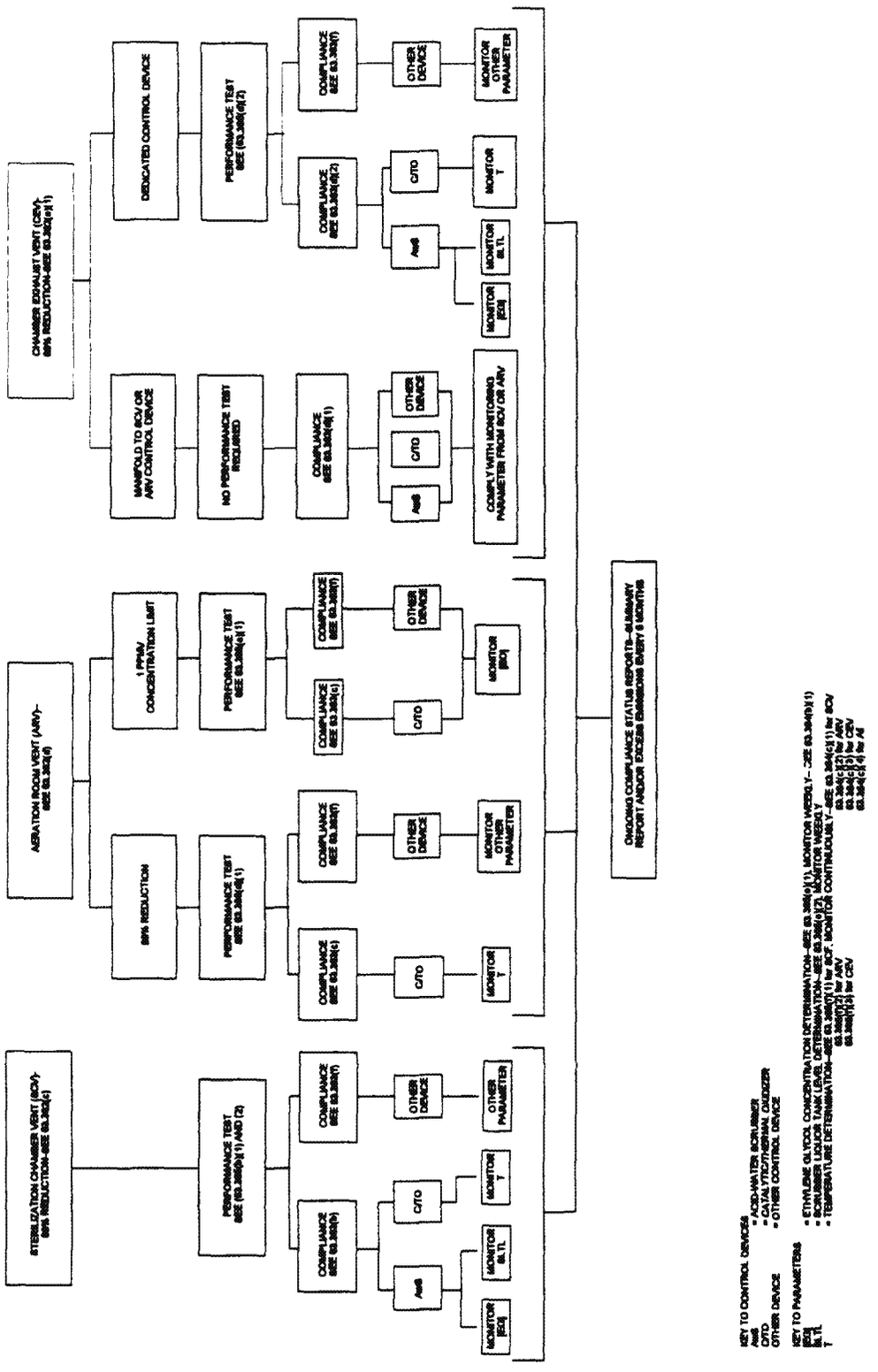


Figure 3-2. Applicability flowchart for sources using 10 tons or more of ethylene oxide per year.

There are two main types of EO sterilization processes: (1) bulk sterilization and (2) single-item sterilization. Using the single-item sterilization process, items are placed in a plastic pouch, sterilant gas is injected into the pouch, and the sealed pouch is placed into an aeration cabinet or room to allow sterilization to occur. Single-item sterilizers typically use much less than 1 ton of EO per year, and therefore, they may only be subject to minimal recordkeeping requirements of the NESHAP. Bulk sterilization is by far the more commonly used EO sterilization process. Using this process, products to be sterilized are placed in a sterilization chamber and are exposed to a sterilant gas at a predetermined temperature, humidity level, and pressure. The equipment, sterilant gases, and sterilization cycle used for bulk sterilization processes are described below.

3.3.1 Equipment

A schematic of a gas sterilizer is shown in Figure 3-3. The main components of the sterilizer are the chamber and vacuum pump. Chambers used by commercial sterilization facilities typically range in volume from 2.8 cubic meters (m^3) (100 cubic feet [ft^3]) to 28 m^3 (1,000 ft^3). A vacuum pump is used to remove air from the chamber before sterilization begins and to evacuate the sterilant gas after the sterilization cycle is complete.

3.3.2 Sterilant Gases

Ethylene oxide is an extremely effective sterilant gas. The EO penetrates product packaging (e.g., cardboard shipping box, plastic shrink wrap, paper box, and product wrapping) and destroys bacteria and viruses on the product. The product remains sterile until use because bacteria and viruses cannot penetrate the product wrapping. The most widely used sterilant gas is a mixture of 12 percent by weight EO and 88 percent by weight dichlorodifluoromethane (CFC-12), referred to as 12/88. Two other commonly used sterilant gases are (1) 100 percent pure EO and (2) a mixture of 10 percent by weight EO and 90 percent by weight carbon dioxide, referred to as 10/90.

3.3.3 Sterilization Cycle

The typical sterilization cycle consists of six phases: (1) presterilization conditioning, (2) sterilization, (3) evacuation, (4) air wash, (5) chamber exhaust, and (6) aeration. Each of these phases is discussed briefly below.

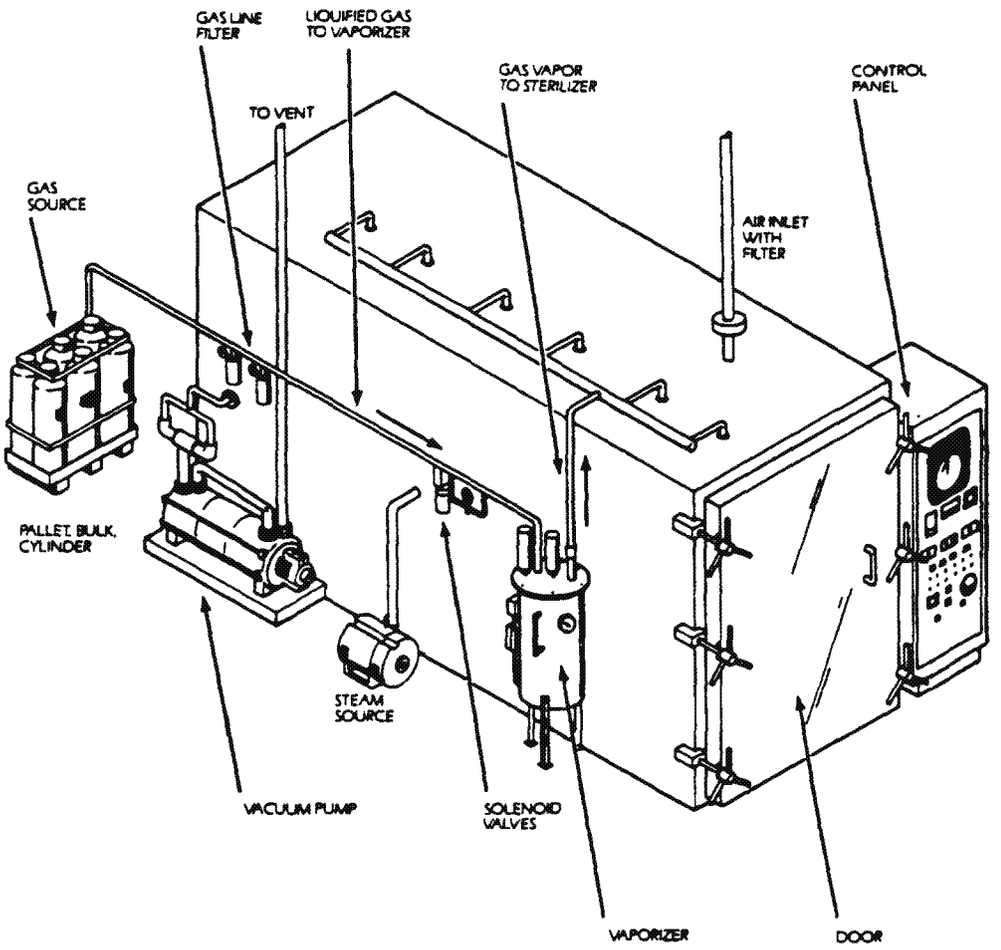


Figure 3-3. Schematic of a gas sterilizer.
(Courtesy of Union Carbide Corporation, Linde Division.)

3.3.3.1 Presterilization Conditioning. After the products have been loaded into the chamber and the airtight door is sealed, a partial vacuum is drawn inside the chamber. This initial vacuum, or drawdown, prevents dilution of the sterilant gas. Also, if flammable gas mixtures are used, the removal of air reduces the potential for ignition. The initial drawdown takes from about 5 to 45 minutes, depending on the product being sterilized. The chamber temperature is adjusted to ensure proper sterilization, and the relative humidity is raised to ensure susceptibility of microorganisms to the sterilant gas.

3.3.3.2 Sterilization. The sterilant, which is supplied as a liquid, is vaporized and introduced into the chamber to achieve the desired concentration of EO. The chamber pressure, which depends on the type of sterilant gas used, is maintained for about 4 to 6 hours.

3.3.3.3 Evacuation. Following sufficient exposure time, the sterilant gas is evacuated from the chamber with a vacuum pump. This postcycle vacuum phase typically lasts about 10 minutes.

3.3.3.4 Air Wash. The pressure in the chamber is bought to atmospheric pressure by introducing either air, nitrogen, or CO_2 (depending on the flammability of the sterilant gas mixture). The combination of evacuation and air wash phases is repeated from two to four times to remove as much of the EO from the product as possible. The purpose of the air washes is to allow residual EO to diffuse from the product to help meet Food and Drug Administration (FDA) guidelines on residual EO levels for medical devices, EPA residual tolerances for agricultural products, and the Occupational Safety and Health Administration (OSHA) standard for exposure in the workplace.

3.3.3.5 Chamber Exhaust. Prior to unloading the sterilizer, the chamber door is automatically cracked, and the chamber exhaust is activated. The chamber exhaust is an exhaust system that evacuates EO-laden air from the chamber prior to unloading and while the chamber is being unloaded (and reloaded). The chamber exhaust is a worker safety system that is responsible for removing EO from the void space in the sterilizer chamber. The chamber exhaust does not dramatically effect residual EO concentrations in the products being sterilized.

3.3.3.6 Aeration. Following their removal from the sterilization chamber, the sterile products are placed in an aeration room and kept there for several hours or days depending on the

product. The purpose of aeration is to allow further diffusion of residual EO from the products prior to shipping in order to comply with the FDA and EPA guidelines for residual EO. Ethylene oxide concentrations in the aeration room are maintained at relatively low levels by ventilating the room at a rate of about 20 air changes per hour. Also, aeration rooms are frequently heated to aid in EO offgasing.

3.3.4 Emission Sources

The four principal sources of EO emissions from sterilization/fumigation processes are the following:

- ✓ Sterilizer vent(s) (i.e., the vent on the vacuum pump gas/liquid separator);
- ✓ Sterilization chamber vacuum pump drain;
- ✓ Chamber exhaust vent(s); and
- ✓ Aeration room vent(s).

A schematic of these emission sources is shown in Figure 3-4.

3.4 NUMBER AND LOCATION OF AFFECTED SOURCES

Approximately 200 EO commercial sterilization and fumigation sources exist in the United States; approximately 150 of these sources are expected to be affected by the NESHAP. Table 3-1 lists the number of facilities by State according to EPA's data base compiled during the development of the NESHAP. Appendix C of this document lists the known facilities that are affected by this regulation.

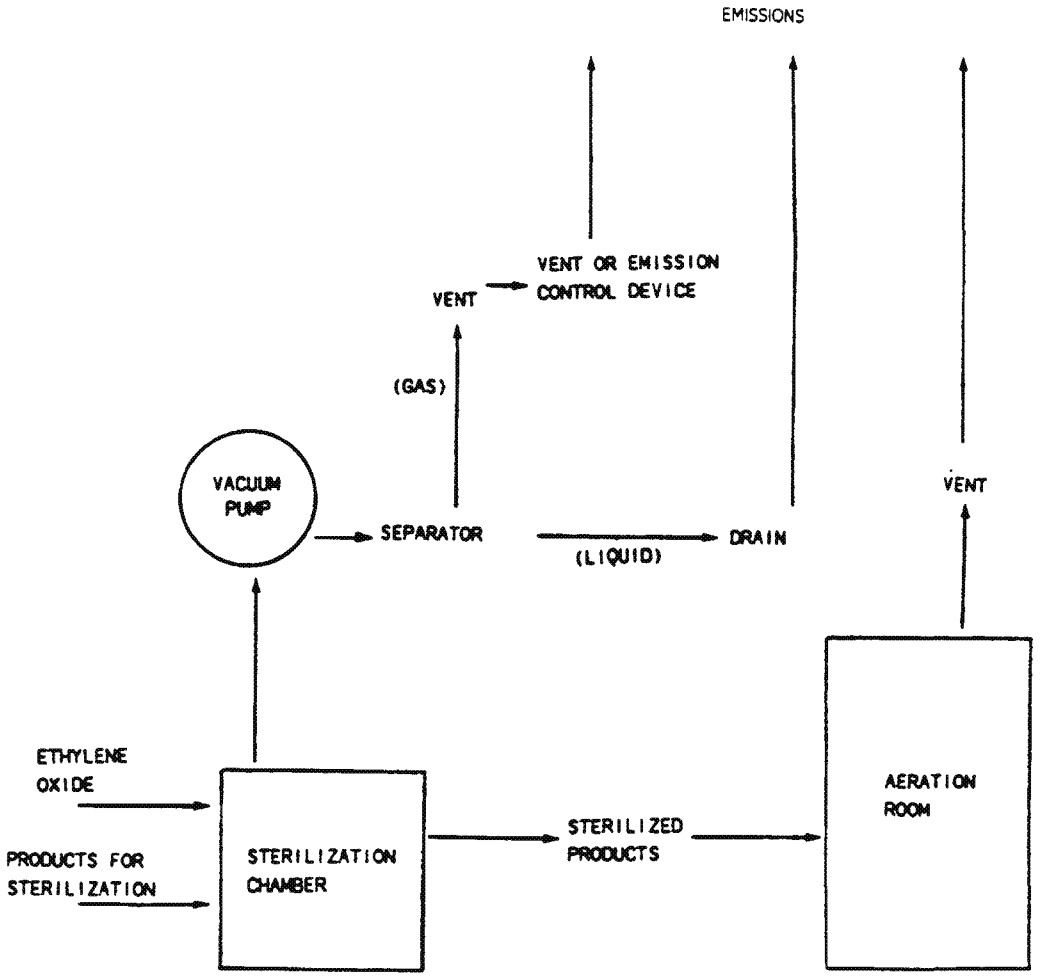


Figure 3-4. Schematic of emission sources at commercial sterilization facilities.

Table 3-1. Number of Facilities per State[a]

State	No. of facilities	State	No. of facilities
Arizona	3	Mississippi	2
Arkansas	2	Missouri	5
California	19	New Hampshire	2
Colorado	3	New Jersey	17
Connecticut	6	New York	13
Delaware	2	North Carolina	7
Florida	5	Ohio	2
Georgia	4	Pennsylvania	9
Illinois	8	Puerto Rico	14
Indiana	4	Rhode Island	2
Iowa	3	South Carolina	2
Maryland	5	Tennessee	3
Massachusetts	9	Texas	12
Michigan	8	Virginia	5
Minnesota	6	Washington	2
One facility is located in each of the following States: Alabama, Hawaii, Kentucky, Maine, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Utah, Wisconsin, and West Virginia.			
		Total No. of facilities	196

[a] Data base of facilities compiled by EPA during the development of the NESHAP.

CHAPTER 4
EMISSION LIMITS AND CONTROL TECHNIQUES

4.1 EMISSION LIMITS

The regulation specifies emissions standards as shown in Table 4-1 and provides reference emission reduction techniques that may be used to comply with the requirements. However, a source may use other emission reduction techniques, as long as the level of emission reduction is the same or better.

Table 4-1. Emissions Reductions and Limits

Source size, yearly EO usage	Emissions standards for each source type		
	Sterilization chamber vent, SCV	Aeration room vent, ARV	Chamber exhaust vent, CEV
<1 ton	No controls required; minimal recordkeeping requirements apply.		
≥1 ton and <10 tons	99% emission reduction	No control	Maximum chamber concentration limit of 5,300 ppmv prior to activation of the chamber exhaust [a]
≥10 tons	99% emission reduction	1 ppmv maximum outlet concentration --OR-- 99% emission reduction	Manifold to a control device used to comply with SCV or ARV standards --OR-- 99 percent emission reduction

[a]Affected sources may show compliance by manifolding emissions to a control device used to comply with the SCV or ARV standards by reducing emissions by at least 99 percent.

4.2 CONTROL TECHNIQUES

As mentioned above, the emission reductions and limits are based on the use of certain control techniques. However, a source may choose to use an alternative control technique, as long as the emission reductions and limits are met. The following paragraphs discuss the control techniques upon which the emissions limits found in Table 4.1 are based.

4.2.1 Acid-water Scrubber

An acid-water scrubber, depicted in Figure 4-1, consists of a countercurrent packed tower, a reaction vessel, and a holding tank. In the countercurrent tower, the sterilant gas contacts an

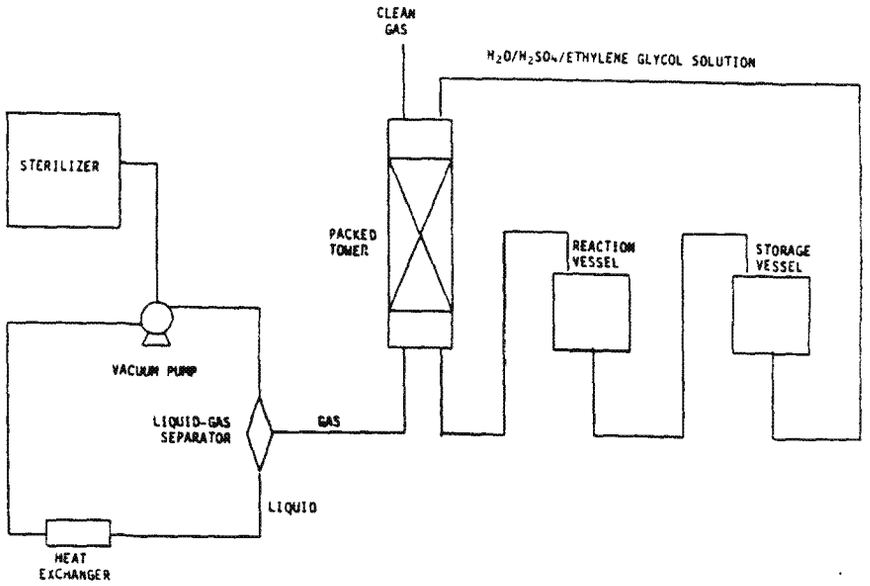


Figure 4-1. Schematic of a typical acid water scrubber system.

acidic water solution, generally aqueous sulfuric acid. Because EO is extremely water soluble, most of the EO is absorbed into the scrubber liquor. Next, the liquor is sent to the reaction vessel, which is a small storage tank operated at atmospheric pressure, to complete the hydrolysis of EO. After the reaction is complete, the liquor is sent to the storage vessel. The liquor in the storage vessel is recirculated to operate the tower until the concentration of ethylene glycol in the liquor reaches a predetermined weight percentage. (At this point the scrubber efficiency declines.) The spent solution is neutralized and then disposed or sold. Typical EO removal efficiencies of acid-water scrubbers are at least 99 percent.

4.2.2 Catalytic Oxidation Unit

Figure 4-2 shows a schematic of a catalytic oxidation unit. If necessary, inlet gas is first mixed with a large volume of air to dilute the control device inlet EO concentration to 5,000 ppmv or less. This dilution prevents excessive catalyst bed temperatures (which can damage the catalyst) from occurring during the oxidation of EO. The gas stream passes through a filter for dust removal and is preheated to the reaction temperature with steam or electricity.

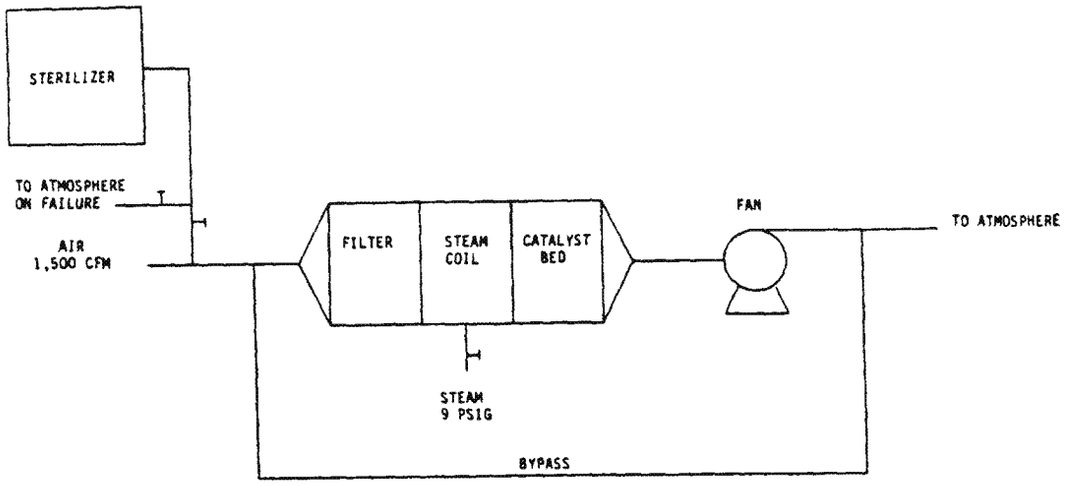


Figure 4-2. Catalytic oxidation system.

The gas then enters the catalyst bed(s), where the EO is oxidized. Because catalytic oxidation is applicable to the control of lower EO concentrations, facilities can manifold several EO emission sources to one control device. In some situations, low-concentration emission sources can provide part or all of the necessary diluent air. Typical EO removal efficiencies of catalytic oxidation units are greater than 99 percent.

4.2.3 Thermal Oxidation Unit

A thermal oxidation unit is depicted in Figure 4-3. Ethylene oxide, which has a high heating value, a relatively low ignition temperature, and a very wide range of mixtures combustible in air, can be easily and efficiently destroyed by thermal oxidation using flares. However, because of difficulties with sustaining combustion, commercially available flares are not applicable for facilities emitting only small amounts of EO. Flares operated within specified conditions of waste gas heat content and flare exit velocity will achieve at least 98 percent EO destruction efficiency.

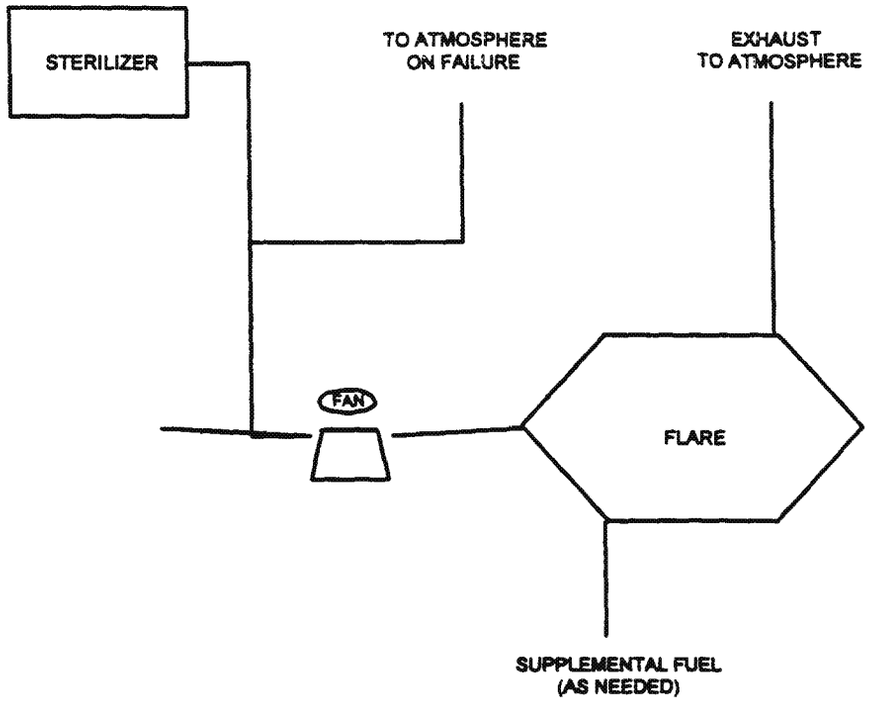


Figure 4-3. Schematic of a typical thermal oxidation system.

CHAPTER 5
DEMONSTRATING COMPLIANCE

There are three components to demonstrating compliance with the emissions standards of this regulation:

- ✓ Initial performance testing
- ✓ Site-specific operating parameters setting
- ✓ Ongoing compliance monitoring

5.1 INITIAL PERFORMANCE TESTING

The initial performance test serves two primary purposes. First, it is necessary to determine if the source is in compliance with the emissions standards listed in Table 4-1 of this document. Second, the initial performance test establishes values for the air pollution control system operating parameters. Monitoring and recording these operating parameters during ongoing sterilization processes will indicate whether or not the source is in compliance with the emissions standards.

Each existing source that is subject to emissions standards is required to perform an initial performance test by June 4, 1998. For sources with an initial startup date of December 8, 1997 or later, the initial performance test must be completed within 180 days after initial startup. Section 63.365 of the regulation specifies test methods and procedures to be used to determine the efficiency of the control devices.

5.2 ESTABLISHING SITE-SPECIFIC OPERATING PARAMETERS

During initial performance testing, applicable air pollution control technique operating parameters must be recorded. These site-specific operating parameters are determined by the air pollution control technique or strategy that the source is using and are listed in Table 5-1. Table 5-1 also refers to the location in the NESHAP for the procedure to be used to establish the site-specific operating parameter.

If a facility chooses to use a control technology other than an acid-water scrubber or catalytic or thermal oxidizer to comply with the emissions standards, the owner or operator of the facility must submit to the appropriate enforcement agency their own recommendations for operating

Table 5-1. Site-specific Operating Parameters

Air pollution control system or strategy	Site-specific operating parameter	Procedure in regulation
Sterilization Chamber Vent (SCV) Standard		
Acid-water scrubber	1. Maximum ethylene glycol concentration in scrubber liquor --OR--	§ 63.365(e)(1)
	2. Maximum scrubber liquor level in recirculation tank	§ 63.365(e)(2)
Catalytic or thermal oxidizer	Baseline temperature during initial performance test	§ 63.365(f)(1)
Aeration Room Vent (ARV) Standard		
Catalytic or thermal oxidizer	Baseline temperature during initial performance test	§ 63.365(f)(2)
Chamber Exhaust Vent (CEV) Standard		
Manifolding emissions to a control device controlling emissions from the SCV and/or the ARV	See appropriate columns above for that vent type and control device	See appropriate columns above.
Not manifolding emissions and using an acid-water scrubber	1. Maximum ethylene glycol concentration in scrubber liquor --OR--	§ 63.365(e)(1)
	2. Maximum scrubber liquor level in recirculation tank	§ 63.365(e)(2)
Not manifolding emissions and using a catalytic or thermal oxidizer	Baseline temperature during initial performance test	§ 63.365(f)(3)

parameters to be established and monitored to indicate proper operation and maintenance of their air pollution control system.

5.3 ONGOING MONITORING

During performance testing, site-specific operating parameters are established, as discussed above. Facilities must continue to monitor these operating parameters to ensure ongoing continuous compliance with the emissions standards. By monitoring and recording the appropriate air pollution control system parameters and comparing the monitored values to the maximum or minimum value established during the performance test, the enforcing agency can determine if the facility is in compliance with the emissions standards. Tables 5-2, 5-3, and 5-4 summarize the ongoing monitoring requirements associated with the sterilization chamber vent standard, aeration room vent standard, and the chamber exhaust vent standard, respectively. Each of these tables includes the equipment specifications and the monitoring frequency, as well as indicators of a violation of the standard for the various air pollution control systems and strategies that may be used.

Table 5-2. Summary of Ongoing Monitoring Requirements for the Sterilization Chamber Vent Standard

Air pollution control system or strategy	Monitored parameter	Monitoring equipment	Frequency	Violation
Acid-water scrubber	1. Ethylene glycol concentration in scrubber liquor --OR--		Once per week[a]	Exceedance of maximum ethylene glycol concentration in scrubber liquor established during initial performance test
	2. Scrubber liquor level in recirculation tank	Liquid level indicator (e.g., marker on tank wall, dipstick, magnetic indicator)	Once per week	Exceedance of maximum scrubber liquor level established during initial performance test
Catalytic or thermal oxidizer	Oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber	1. Temperature monitor accurate to within ±10°F [b] --AND--	Continuously	Oxidation temperature, averaged over 3 cycles, more than 10°F below baseline temperature established during initial performance test
		2. Data acquisition system [c]		

[a]Monitoring is only required during weeks when the scrubber unit has been operated.
[b]Accuracy of temperature monitor must be verified twice each calendar year using a reference temperature monitor.
[c]The data acquisition system must compute and record the average oxidation temperature over the length of the sterilization cycle (based on the length of cycle used during the performance test) and a three-cycle block average every third cycle.

Table 5-3. Summary of Ongoing Monitoring Requirements for the Aeration Room Vent Standard

Air pollution control system or strategy	Monitored oarameter	Monitoring equipment	Frequency	Violation
Catalytic or thermal oxidizer	Oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber	1. Temperature monitor accurate to within ±10°F [a] --AND-- 2. Data acquisition system [b]	Continuously	Oxidation temperature, averaged over 3 hours, more than 10°F below baseline temperature established during initial performance test
Direct measurement of EO concentration	EO concentration at outlet to atmosphere from ARV after any control device	Gas chromatograph [c]	Once per hour and compute 3-hour average every third hour	3-hour average EO concentration in excess of 1 ppmv EO concentration limit

[a] Accuracy of temperature monitor must be verified twice each calendar year using a reference temperature monitor.

[b] The data acquisition system must compute and record the average oxidation temperature each hour and a 3-hour block average every third hour.

[c] Facility must install, calibrate, operate, and maintain gas chromatograph consistent with performance specification 9 in 40 CFR part 60, Appendix B. Daily calibration is only required on days when EO emissions are vented to a control device from the ARV.

Table 5-4. Summary of Ongoing Monitoring Requirements for the Chamber Exhaust Vent Standard

Air pollution control system or strategy	Monitored parameter	Monitoring equipment	Frequency	Violation
Not manifolding emissions and using an acid-water scrubber	1. Ethylene glycol concentration in scrubber liquor --OR--	N/A?	Once per week [a]	Exceedance of maximum ethylene glycol concentration in scrubber liquor established during initial performance test
	2. Scrubber liquor level in recirculation tank	Liquid level indicator (e.g., marker on tank wall, dipstick, magnetic indicator)	Once per week	Exceedance of maximum scrubber liquor level established during initial performance test
Not manifolding emissions and using a catalytic or thermal oxidizer	Oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber	1. Temperature monitor accurate to within ±10°F [b] --AND--	Continuously	Oxidation temperature, averaged over cycle, more than 10°F below baseline established during initial performance test
		2. Data acquisition system[c]		
Direct measurement of EO concentration	EO concentration in sterilization chamber immediately before chamber exhaust is activated	Gas chromatograph[d]	Before chamber exhaust is activated	Exceedance of 5,300 ppmv EO concentration standard
Manifolding emissions to a control device controlling emissions from the SCV and/or the ARV	See appropriate columns in Tables 5-2 and 5-3 for that vent type and control device			

[a] Monitoring is only required during weeks when the scrubber unit has been operated.

[b] Accuracy of temperature monitor must be verified twice each calendar year using a reference temperature monitor.

[c] The data acquisition system must compute and record the average oxidation temperature over the length of the sterilization cycle (based on the length of cycle used during the initial performance test).

[d] Facility must install, calibrate, operate, and maintain gas chromatograph consistent with Performance Specification 9 in 40 CFR Part 60, Appendix B. Daily calibration is only required on days when the chamber exhaust is activated.

CHAPTER 6
RECORDKEEPING AND REPORTING REQUIREMENTS

Most of the recordkeeping and reporting requirements are not detailed in the NESHAP. Instead, they are contained in the General Provisions to part 63 and simply referenced in Table 1 of Section 63.360 in the NESHAP. This table provides specific references to those sections of the General Provisions that apply to the commercial sterilization and fumigation NESHAP. The EPA chose to reference the recordkeeping and reporting requirements of the General Provisions to help reduce unnecessary repetitiveness, and to help provide consistency between the different NESHAP in part 63.

6.1 RECORDKEEPING

The regulation requires sources to keep records to document compliance status with the regulation. These records include:

- ✓ Malfunction records
- ✓ Records to demonstrate compliance
- ✓ Performance test results
- ✓ Continuous monitoring system records
- ✓ Documentation supporting initial notification and notification of compliance status
- ✓ EO usage records for sources not subject to emissions standards

These records must be maintained in a form suitable and readily available for expeditious inspection and review. They may be maintained on microfilm, computer, computer floppy disks, magnetic tape disks, or microfiche. The files must be retained for at least 5 years, and the most recent 2 years of data must be retained on site.

6.1.1 Malfunction Records

Sources must maintain records of the occurrence and duration of each malfunction of the air pollution control equipment. Records of each period during which a CMS is malfunctioning or inoperative (including out-of-control periods) are also required.

6.1.2 Records to Demonstrate Compliance

Sources are also required to maintain records of all required measurements needed to demonstrate compliance with the standard. These records should include the data compiled

according to Tables 5-2, 5-3 and 5-4 of this document, which detail the monitoring requirements of the NESHAP.

6.1.3 Performance Test Results

Sources must maintain records of all results of performance tests and CMS performance evaluations, as well as all measurements necessary to determine the conditions of performance tests and performance evaluations.

6.1.4 Continuous Monitoring System Records

Records relating to CMS must include: (1) all CMS calibration checks; (2) all adjustments and maintenance performed on CMS; (3) all required CMS measurements (including monitoring data recorded during unavoidable CMS breakdowns and out-of-control periods); (4) the date and time identifying each period during which the CMS was inoperative except for zero (low-level) and high-level checks; (5) the specific identification (i.e., the date and time of commencement and completion) of each time period of excess emissions and parameter monitoring exceedances that occurs during periods other than startups, shutdowns, and malfunctions of the source; (6) the nature and cause of any malfunction (if known); the corrective action taken or preventive measures adopted; (7) the nature of the repairs or adjustment to the CMS that was inoperative or out of control; (8) the total process operating time during the reporting period; and (9) all procedures that are part of a quality control program developed and implemented for CMS.

6.1.5 Documentation Supporting Initial Notification and Notification of Compliance Status

Sources are required to maintain all documentation supporting the initial notifications and notifications of compliance status required by the NESHAP.

6.1.6 Records for Sources Not Subject to Emissions Standards

Sources that use 1 to 10 tons of EO per year and that are not subject to emissions standards (see Table 4-1 of this document) are only required to keep records of EO usage on a 12-month rolling basis. Sources that use less than 1 ton of EO per year are also only required to keep EO usage records on a 12-month rolling basis.

6.2 REPORTING

The regulation requires that sources submit reports and notifications, which include:

- ✓ Initial notification
- ✓ Notification of construction/reconstruction
- ✓ Notification of performance test and CMS performance evaluation
- ✓ Test plans (to be submitted upon request)
- ✓ Notification of compliance status
- ✓ Excess emission and CMS performance report/summary report

All reports must be submitted to the Administrator (i.e., the appropriate EPA Regional Office or the delegated State or local authority). The required reports may be sent by U. S. Mail, fax, or by another courier (including electronic submission).

6.2.1 Initial Notification

Sources with an initial startup date before December 6, 1994 were required to submit an initial notification to the Administrator on or before April 5, 1995 (120 days after the effective date of the standards). New or reconstructed sources with an initial startup date after December 6, 1994 are required to submit an initial notification within 120 calendar days after the source becomes subject to the standards. The initial notification includes the following information: (1) the name and address of the owner or operator; (2) the physical address of the source; (3) an identification of the relevant standard or other requirement and the source's compliance date; (4) a brief description of the nature, size, design, and method of operation of the source; and (5) a statement of whether the source is a major source or an area source.

6.2.2 Notification of Construction/Reconstruction[2]

Sources must apply for approval of the construction of a new affected source. Sources must also apply prior to the reconstruction of a nonaffected source if the reconstruction would result in

[2]The construction/reconstruction requirements of the General Provisions to Part 63 (Subpart A) are undergoing revisions as of the publication date of this implementation document. Readers are encouraged to consult future *Federal Register* notices for the latest construction/ reconstruction information.

the source being an affected source. All applications must be submitted to the Administrator as soon as practicable to ensure timely review.

6.2.3 Notification of Performance Test and CMS Performance Evaluation

Sources must notify the Administrator in writing of intent to conduct an initial performance test at least 60 calendar days before the scheduled date of the test to allow the Administrator to review and approve their site-specific test plan and to have an observer present at the test. Simultaneously with this notification, the source will also notify the Administrator of the date of the continuous monitoring system (CMS) performance evaluation. The Administrator may or may not choose to have an observer present. If the scheduled date for the test is changed for unforeseen reasons, the source will inform the Administrator within 5 calendar days of the originally scheduled test date and will specify the date of the rescheduled test.

6.2.4 Test Plans

Before conducting the initial performance test, sources are required to develop and, if requested by the Administrator, submit a site-specific test plan and a CMS performance evaluation test plan to the Administrator for approval. The test plan will include: (1) a test program summary, (2) the test schedule, (3) data quality objectives (i.e., pretest expectations of precision, accuracy, and completeness of data), (4) an internal and external quality assurance (QA) program. The CMS performance evaluation test plan will include: (1) the evaluation program summary, (2) the performance evaluation schedule, (3) data quality objectives, and (4) both an internal an external QA program. If requested by the Administrator, the source will submit these test plans at least 60 calendar days before the performance test is scheduled to take place. The Administrator will then either approve or disapprove the test plans within 30 calendar days after receipt of the plans.

6.2.5 Notification of Compliance Status

Sources are required to submit a notification of compliance status within 60 days after the initial performance test. The notification must include: (1) the methods that were used to determine compliance; (2) the results of the performance test and the CMS performance evaluation; (3) the methods that will be used for determining continuing compliance; (4) the type and quality of HAPs emitted, reported in units and averaging times specified in the regulation;

(5) an analysis demonstrating whether the source is a major source or an area source; (6) a description of the air pollution control equipment (or method) for each emission point, including the control efficiency for each control device (or method); and (7) a statement as to whether the source has complied with the relevant standard or other requirements.

6.2.6 Excess Emissions and CMS Performance Report/Summary Report

Sources are required to submit an excess emissions and CMS performance report and/or a summary report to the Administrator semiannually. These reports are due 30 calendar days after each half of the calendar year (i.e., July 30 and January 30). A summary report may be submitted in lieu of the full excess emissions and CMS performance report if the total duration of excess emissions or process or control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and if the CMS downtime of the reporting period is less than 5 percent of the total operating time for the reporting period. Otherwise, the summary report and the excess emissions and CMS performance report is required.

The summary report must include: (1) the company name and address of the source; (2) an identification of each HAP monitored at the source; (3) the beginning and ending dates of the reporting period; (4) a brief description of the process units; (5) the relevant emission and operating parameter limitations specified in the NESHAP; (6) the monitoring equipment and manufacturer(s) and model number(s); (7) the date of the latest CMS certification or audit; (8) the total operating time of the source during the reporting period; (8) an emission data summary, including the total duration of excess emissions during the reporting period, the total during of excess emissions expressed as a percent of the total source operating time during that reporting period;, and a breakdown of the total duration of excess emissions during the reporting period into those that are due to startup/shutdown, control equipment problems, process problems, other known causes, and other unknown causes; (9) a CMS performance summary, including the total CMS down time during the reporting period, the total duration of CMS downtime expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total CMS downtime during the reporting period into periods that are due to monitoring equipment malfunctions, nonmonitoring equipment malfunctions, quality assurance/quality

control calibration, other known causes, and other unknown causes; (10) a description of any changes in CMS, processes, or controls since the last reporting period; (11) the name, title, and signature of the responsible official who is certifying the accuracy of the report; and (12) the date of the report.

The excess emissions and CMS performance report must include: (1) the name, title, and signature of the responsible official who is certifying the accuracy of the report; (2) information from any calibration tests in which the monitoring equipment is not in compliance with performance specification (PS) -9 of 40 CFR part 60 or the method used for temperature calibration; (3) the date and time identifying each period during which the CMS was inoperative, except for zero (low-level) and high-level checks; (4) the date and time identifying each period during which the CMS was out of control; (5) the date and time of commencement and completion of each period of excess emissions and parameter monitoring exceedances that occurs during startups, shutdowns, and malfunction of the source; (6) the date and time of commencement and completion of each period of excess emissions and parameter monitoring exceedances that occurs during periods other than startups, shutdowns, and malfunctions of the source; (7) the nature and cause of any malfunction (if known); (8) the corrective action taken or preventive measures adopted; (9) the nature of the repairs or adjustment to the CMS that was inoperative or out of control; and (10) the total process operating time during the reporting period. When no excess emissions or exceedances have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information should be stated in the report.

CHAPTER 7
INSPECTION PROCEDURES

The following comprise sample checklists that may be used during inspections of affected sources.

INSPECTION CHECKLIST

PART A. GENERAL PROCESS INFORMATION

Applicable Rule: 40 CFR Part 63, Subpart O—NESHAP for Ethylene Oxide Commercial Sterilization and Fumigation Operations.

Plant Name _____

Plant Address _____

_____

City_____ State_____ Zip Code_____

Plant Contact/Title_____Plant Phone number _____

Owner/Operator, Title_____

Street Address (if different than plant's)_____

_____

City_____ Sate_____ Zip Code _____

1. Inspection Date: ___/___/___ Time:_____
2. Indicate whether a facility is a new or existing source:

   ___ New source ___ Existing source
3. Indicate the facility's compliance date: ___/___/___
4. Indicate the facility's annual EO use in previous 12 months: _____
5. Indicate the facility's compliance approach

   Sterilization chamber vent:

   ___ Acid-Water scrubber ___ Oxidizer ___ Other (_____)

   Chamber exhaust vent:

   ___ 5,300 ppm limit ___ Manifolded to control device ___ Dedicated control device

   ___ Acid-Water scrubber ___ Oxidizer ___ Other (_____)

   Aeration room vent:

   ___ 1 ppm max ___ Manifolded to control device ___ Dedicated control device

   ___ Acid-Water scrubber ___ Oxidizer ___ Other (_____)

Investigator/Title:_____Date:___/___/___

_____

INSPECTION CHECKLIST

PART B. MONITORING REQUIREMENTS FOR STERILIZATION CHAMBER VENTS

Inspection steps	Value	Y	N	Inspector notes
General				
1. From Part A of the Inspection Checklist, determine the dedicated control device used to comply with the standard.				
2. Determine that source has complied with the requirements for the appropriate dedicated control device; follow the inspection steps listed on the appropriate forms:				

Inspection	Value	Y	N	Inspector notes
Acid-Water Scrubbers				
1. Enter the site-specific operating parameter value established during the initial performance test (i.e., either the maximum ethylene glycol concentration in the scrubber liquor or the maximum scrubber liquor level in the recirculation tank).				
2. Obtain records of ongoing monitoring data.				
3. Answer (a) or (b): (a) Has the ethylene glycol concentration in the scrubber liquor been monitored and recorded once per week? (b) Has the scrubber liquor level in the recirculation tank been monitored and recorded once per week?				
4. Answer (a) or (b): (a) Has the source exceeded the maximum ethylene glycol concentration in the scrubber liquor established during the initial performance test? (b) Has the source exceeded the maximum scrubber liquor level established during the initial performance test?				
5. If the answer to step 4 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

Inspection steps	Value	Y	N	Inspector notes
Thermal or Catalytic Oxidizers				
1. Obtain and enter the site-specific operating parameter value established during the initial performance test (i.e., oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber).				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a temperature monitor accurate to within ±10°F as verified twice each calendar year with a reference temperature monitor?				
4. Does the source operate a data acquisition system that computes and records the average oxidation temperature over the length of the cycle and a three-cycle block average every third cycle?				
5. Has the oxidation temperature, averaged over 3 cycles, been more than 10°F below the baseline temperature established during the initial performance test?				
6. If the answer to step 5 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

Inspection steps	Value	Y	N	Inspector notes
Other Control Devices				
1. Enter the site-specific operating parameter value established during the initial performance test.				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a monitoring device(s) accurate to within the tolerances in the site specific monitoring plan approved by the Administrator and verified in accordance with this plan?				
4. Does the source operate a data acquisition system that computes and records a monitoring parameter(s) according to the schedule specified in the site specific monitoring plan approved by the Administrator?				
5. Have the recorded values shown violation of the parameters?				
6. If the answer to step 5 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

INSPECTION CHECKLIST

PART C. MONITORING REQUIREMENTS FOR CHAMBER EXHAUST VENTS

Step in inspection	Value	Y	N	Inspector notes
General				
1. From Part A of the Inspection Checklist, determine the method of compliance: (a) Monitor EO concentration. Go to Step 2. (b) Manifold emissions to control device. Go to Step 5. (c) Emissions controlled via dedicated control device. Go to Step 6.				
2. Obtain records of ongoing monitoring data.				
3. Has the ethylene oxide concentration exceeded the 5,300 ppm limit?				
4. If the answer to step 3 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				
5. Determine that source has complied with the requirements for that control device on that emissions point (continue on Part B, or Part D as appropriate).				
6. Determine that source has complied with the requirements for the appropriate dedicated control device as follows:				

Step in inspection	Value	Y	N	Inspector notes
Acid-Water Scrubbers				
1. Enter the site-specific operating parameter value established during the initial performance test (i.e., either the maximum ethylene glycol concentration in the scrubber liquor or the maximum scrubber liquor level in the recirculation tank).				
2. Obtain records of ongoing monitoring data.				
3. Answer (a) or (b): (a) Has the ethylene glycol concentration in the scrubber liquor been monitored and recorded once per week? (b) Has the scrubber liquor level in the recirculation tank been monitored and recorded once per week?				
4. Answer (a) or (b): (a) Has the source exceeded the maximum ethylene glycol concentration in the scrubber liquor established during the initial performance test? (b) Has the source exceeded the maximum scrubber liquor level established during the initial performance test?				
5. If the answer to step 4 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

RECORDING AND REPORTING REQUIREMENTS

Step in inspection	Value	Y	N	Inspector notes
Thermal or Catalytic Oxidizers				
1. Enter the site-specific operating parameter value established during the initial performance test (i.e., oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber).				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a temperature monitor accurate to within ±10°F as verified twice each calendar year with a reference temperature monitor?				
4. Does the source operate a data acquisition system that computes and records the average oxidation temperature over the length of the cycle and a three-cycle block average every third cycle?				
5. Has the oxidation temperature, averaged over 3 cycles, been more than 10°F below the baseline temperature established during the initial performance test?				
6. If the answer to step 5 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

Step in inspection	Value	Y	N	Inspector notes
Other Control Devices				
1. Enter the site-specific operating parameter value established during the initial performance test.				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a monitoring device(s) accurate to within the tolerances in the site specific monitoring plan approved by the Administrator and verified in accordance with this plan?				
4. Does the source operate a data acquisition system that computes and records a monitoring parameter(s) according to the schedule specified in the site specific monitoring plan approved by the Administrator?				
5. Have the recorded values shown violation of the parameters?				
6. If the answer to step 5 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

INSPECTION CHECKLIST

PART D. MONITORING REQUIREMENTS FOR AERATION ROOM VENTS

Step in inspection	Value	Y	N	Inspector notes
		General		
1. From Part A of the Inspection Checklist, determine the method of compliance: (a) Monitor EO concentration. Go to Step 2. (b) Manifold emissions to control device. Go to Step 5. (c) Emissions controlled via dedicated control device. Go to Step 6.				
2. Obtain records of ongoing monitoring data.				
3. Has the ethylene oxide concentration exceeded the 1 ppm limit?				
4. If the answer to step 3 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				
5. Determine that source has complied with the requirements for that control device on that emissions point (continue on Part B, or Part D as appropriate).				
6. Determine that source has complied with the requirements for the appropriate device as follows:				

Step in inspection	Value	Y	N	Inspector notes
Acid-Water Scrubbers				
1. Enter the site-specific operating parameter value established during the initial performance test (i.e., either the maximum ethylene glycol concentration in the scrubber liquor or the maximum scrubber liquor level in the recirculation tank).				
2. Obtain records of ongoing monitoring data.				
3. Answer (a) or (b): (a) Has the ethylene glycol concentration in the scrubber liquor been monitored and recorded once per week? (b) Has the scrubber liquor level in the recirculation tank been monitored and recorded once per week?				
4. Answer (a) or (b): (a) Has the source exceeded the maximum ethylene glycol concentration in the scrubber liquor established during the initial performance test? (b) Has the source exceeded the maximum scrubber liquor level established during the initial performance test?				
5. If the answer to step 4 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

Step in inspection	Value	Y	N	Inspector notes
Thermal or Catalytic Oxidizers				
1. Enter the site-specific operating parameter value established during the initial performance test (i.e., oxidation temperature at outlet to catalyst bed or at exhaust point from thermal combustion chamber).				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a temperature monitor accurate to within ±10°F as verified twice each calendar year with a reference temperature monitor?				
4. Does the source operate a data acquisition system that computes and records the average oxidation temperature over the length of the cycle and a three-cycle block average every third cycle?				
5. Has the oxidation temperature, averaged over 3 cycles, been more than 10°F below the baseline temperature established during the initial performance test?				
6. If the answer to step 5 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

Step in inspection	Value	Y	N	Inspector notes
Other Control Devices				
1. Enter the site-specific operating parameter value established during the initial performance test.				
2. Obtain records of ongoing monitoring data.				
3. Does the source operate a monitoring device(s) accurate to within the tolerances in the site specific monitoring plan approved by the Administrator and verified in accordance with this plan?				
4. Does the source operate a data acquisition system that computes and records a monitoring parameter(s) according to the schedule specified in the site specific monitoring plan approved by the Administrator?				
5. Have the recorded values shown violation of the parameters?				
6. If the answer to step 5 is "Yes," has the source reported the excess emissions to the Administrator? Stop here.				

INSPECTION CHECKLIST

PART D. RECORDKEEPING REQUIREMENTS

Step in inspection	Y	N	Inspector notes
1. Does the source use less than 10 tons of ethylene oxide per year? If "Yes," go to Step 2. If "No," go to Step 4.			
2. Is the source subject to emissions limitations in the regulation? If "Yes," go to Step 4. If "No," go to Step 3.			
3. Does the source maintain records of EO usage on a 12-month rolling basis? Stop here.			
4. Does the source maintain the following malfunction records: (a) The occurrence and duration of each malfunction of the air pollution control equipment; AND (b) Records of each period during which a continuous monitoring system is malfunctioning or inoperative (including out-of-control periods)?			
5. Does the source maintain records of all required measurements needed to demonstrate compliance with the standard?			
6. Does the source maintain records of all results of performance tests and CMS performance evaluations, as well as all measurements as may be necessary to determine the conditions of the performance tests and evaluations?			

Step in inspection	Y	N	Inspector notes
7. Does the source maintain the following records relating to CMS: (a) All CMS calibration checks; (b) All adjustments and maintenance performed on CMS; (c) All required CMS measurements (including monitoring data recorded during unavoidable CMS breakdowns and out-of-control periods); (d) The date and time identifying each period during which the CMS was inoperative except for zero (low-level) and high-level checks; (e) The specific identification (i.e., the date and time of commencement and completion) of each time period of excess emissions and parameter monitoring exceedances tat occurs during periods other than startups, shutdowns, and malfunctions of the source; (f) The nature and cause of any malfunction (if know); the corrective action taken or preventive measures adopted; (g) The nature of the repairs or adjustment to the CMS that was inoperative or out of control; (h) The total process operating time during the reporting period; and (I) All procedures that are part of a quality control program developed and implemented for CMS?			

CHAPTER 8
COMMONLY ASKED QUESTIONS AND ANSWERS

Q: Am I a major source?

A: The term "major source" refers to a category of stationary sources that are regulated for emissions of hazardous air pollutants (HAP's) under Section 112 of the Clean Air Act. Your facility is a major source if it emits or has the potential to emit, after air pollution controls, 10 tons per year of any one hazardous pollutant or 25 tons per year of any combination of HAP's. Facilities that emit lesser quantities of HAP's are "area sources." The term "area" is used rather than "non-major" or "minor" to emphasize that while individual facilities are smaller, their aggregate emissions are still a concern, especially in urban areas containing many facilities. Ethylene oxide is designated as a hazardous air pollutant.

Q: In terms of the requirements of this standard, 40 CFR Part 63, Subpart O, does it matter whether I am a major or area source?

A: No. Some of the National Emission Standards for Hazardous Air Pollutants (NESHAP) do differentiate between major and area sources and some only regulate the major sources. However, this standard, 40 CFR Part 63, Subpart O (Sterilizer NESHAP), regulates both major and area sources.

Q: Does my ethylene oxide usage have an impact on the requirements of the Sterilizer NESHAP?

A: Yes. If your facility uses less than 1 ton of ethylene oxide per year (all consecutive 12-month periods after December 6, 1996), you are subject to only the recordkeeping requirements of the standard (Section 63.367). If you use 1 or more tons of ethylene oxide per year, you are also subject to the emission standards of the Sterilizer NESHAP. Which emission standards apply to you depend on whether or not you use 10 or more tons of ethylene oxide per year. Please note that how the standards apply to you is based on ethylene oxide usage, not ethylene oxide emissions. The basis here is different from that used to determine whether you are a major or area source.

Q: When do I need to comply with the Sterilizer NESHAP?

A: If the startup of your sterilization facility occurred on or before December 8, 1997, your compliance date is December 8, 1997. If your startup will be after December 8, 1997, your compliance date is the date of startup. As of your compliance date, you are required to meet all standards that apply to you, depending on your ethylene oxide usage (see Question 3).

If the Sterilizer NESHAP emission standards apply to your facility, you will need to conduct initial performance testing within 180 days of your compliance date or by June 8, 1998, if your compliance date is December 8, 1997. The performance testing is conducted with the methods and procedures in Sections 63.7 and 63.365. Performance testing will determine the values to be used for compliance monitoring at your facility. Monitoring requirements are described in Section 63.364 of the Sterilizer NESHAP and come into effect on the date of completion of the initial performance test.

Q: *What does the Title V permit deferral I've heard about have to do with what I'm required to do for this standard (Sterilizer NESHAP)?*

A: On June 3, 1996, the USEPA published an amendment to the Sterilizer NESHAP in the *Federal Register* (61 FR 27785). In its original form, the Sterilizer NESHAP required that subject sources using 1 ton or more obtain a Title V permit. The amendment revises Section 63.360(f) to state that subject sources which use 1 ton, but are not major or located at major sources, may be deferred by the applicable Title V permitting authority from the Title V permitting requirements for 5 years until December 9, 1999. Most States have indicated that they will grant these deferrals. This means that if you are an area source using 1 ton per year, you have until December 9, 2000, to submit your Title V permit application, unless your State agency specifies an earlier deadline.

The deferral of the Title V application deadline does NOT affect the compliance deadline of the Sterilizer NESHAP. Therefore, if your company is an area source using 1 ton, you must be in compliance with the emission standards by December 8, 1997.

Q: *How does combining my emissions from two or more emissions points to one control device affect my initial compliance test and ongoing monitoring?*

A: In certain circumstances, it is possible to combine the emissions flows from multiple emissions points to a single emissions control device (e.g., combine the emissions from the sterilizer vent and aeration room to a catalytic oxidizer). If such an approach were attempted, the owner or operator would need to obtain prior approval from the delegated State agency. In addition, during the initial compliance test, the emissions points would need to be isolated so that the monitoring parameters may be accurately determined. After initial compliance is determined, the emissions may be manifolded to a common control device provided that the monitoring parameter limits determined during the initial compliance test are not exceeded.

Q: I determined initial compliance with the aeration room vent standards by calculating the percent reduction in emissions, must I continue to calculate the percent reduction to satisfy the ongoing monitoring requirements?

A: The aeration room vent standards for sources using 10 or more tons of EO per year require either a 99 percent emission reduction or a maximum EO concentration of 1 ppmv. The standards do not require a source to commit to either approach. Therefore, it would be possible for a source to determine initial compliance with the standards by calculating their percent reduction in aeration room vent emissions, and then comply with the 1 ppmv concentration limit to show ongoing compliance.

APPENDIX A

GLOSSARY OF TERMS

Administrator means the Administrator of the United States Environmental Protection Agency of his or her authorized representative (e.g., a State that has been delegated the authority to implement the provisions of 40 CFR part 63).

Aeration room means any vessel or room that is used to facilitate off-gassing of ethylene oxide at a sterilization facility.

Aeration room vent means the point(s) through which the evacuation of ethylene oxide-laden air from an aeration room occurs.

Area source means any stationary source of hazardous air pollutants that is not a major source as defined below in this appendix. Another term for area source is "nonmajor source."

Baseline temperature means any temperature at the outlet point of a catalytic oxidation unit control device or at the exhaust point from the combustion chamber for a thermal oxidation unit control device established during the performance test when the respective unit achieves at least 99-percent control of ethylene oxide emissions.

Chamber exhaust vent means the point(s) through which ethylene oxide-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes.

Compliance date means the date by which a source subject to the emissions standards in § 63.362 is required to be in compliance with the standard.

Effective date means the date of promulgation in the *Federal Register* notice (December 6, 1994).

Initial startup date means the date when a source subject to the emissions standards in § 63.362 first begins operation of a sterilization process.

Major source means any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls in the aggregate, 10 tons per year or more of any hazardous air pollutant, or 25 tons per year or more of any combination of hazardous air pollutants.

Manifolding emissions means combining ethylene oxide emissions from two or more different vent types for the purpose of controlling these emissions with a single control device.

Maximum ethylene glycol concentration means any concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Maximum liquor tank level means any level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Operating parameter value means a minimum or maximum value established for a control device or process parameter which, if achieved by itself or in combination with one or more other operating parameter values, determines that an owner or operator is in continual compliance with the applicable emission limitation standard.

Oxidation temperature means the temperature at the outlet point of a catalytic oxidation unit control device or at the exhaust point from the combustion chamber for a thermal oxidation unit control device.

Parametric monitoring means monitoring of a specific operating parameter of the control device that demonstrates that the control device is operating under conditions that meet the standard.

Research or laboratory operation means an operation whose primary purpose is for research and development of new processes and products, that is conducted under the close supervision of technically trained personnel, and that is not involved in the manufacture of products for commercial sale in commerce, except in a de minimis manner.

Source(s) using less than 1 ton means source(s) using less than 907 kg (1 ton) of ethylene oxide within all consecutive 12-month periods after December 6, 1996.

Source(s) using 1 ton means source(s) using 907 kg (1 ton) or more of ethylene oxide within any consecutive 12-month period after December 6, 1996.

Source(s) using 1 to 10 tons means source(s) using 907 kg (1 ton) or more of ethylene oxide in any consecutive 12-month period but less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

Source(s) using less than 10 tons means source(s) using less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

Source(s) using 10 tons means source(s) using 9,070 kg (10 tons) or more of ethylene oxide in any consecutive 12-month period after December 6, 1996.

Sterilization chamber means any enclosed vessel or room that is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility.

Sterilization chamber vent means the point (prior to the vacuum pump) through which the evacuation of ethylene oxide from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.

Sterilization facility means any stationary source where ethylene oxide is used in the sterilization or fumigation of materials.

Sterilization operation means any time when ethylene oxide is removed from the sterilization chamber through the sterilization chamber vent or the chamber exhaust vent or when ethylene oxide is removed from the aeration room through the aeration room vent.

APPENDIX B.
DETAILED TABLE OF CONTENTS OF THE REGULATION

Table B-1. Detailed Table of Contents of the Regulation

Section in regulation	Contents or Requirement
§ 63.360 Applicability	
§ 63.360(a)	Sources using ≥ 1 ton EO per year subject to rule (including subpart A)
§ 63.360(b)	Sources using <1 ton EO per year only subject to recordkeeping in § 63.367(c)
§ 63.360(c)	Exemption for beehive fumigation sources
§ 63.360(d)	Exemption for research and development sources
§ 63.360(e)	Exemption for medical facilities
§ 63.360(f)	Sources using ≥ 1 ton EO per year must obtain title V permit
§ 63.360(g)	Compliance dates (CD):
§ 63.360(g)(1)	• Startup before 12/8/97 ⇒ CD = 12/6/97
§ 63.360(g)(2)	• Startup after 12/8/97 ⇒ CD = startup date
§ 63.360(g)(3)	• Increase EO usage after 12/8/97 ⇒ CD = date of increase
§ 63.361 Definitions	
§ 63.361	Definitions of terms used in regulation
§ 63.362 Standards	
§ 63.362(a)	Comply with standards as of CD for source
§ 63.362(b)	Standards apply only during sterilization operation, not during malfunctions
§ 63.362(c)	Sterilization chamber vent (SCV) (sources using ≥ 1 ton) ⇒ 99 percent reduction
§ 63.362(d)	Aeration room vent (ARV) (sources using ≥ 10 tons) ⇒ 99 percent reduction or 1 ppmv EO
§ 63.362(e)	Chamber exhaust vent (CEV) standards:
§ 63.362(e)(1)	• Sources using ≥ 10 tons ⇒ manifold to SCV or ARV or 99 percent reduction
§ 63.362(e)(2)	• Sources using 1 to 10 tons ⇒ 5,300 ppmv EO; may manifold to SCV or 99 percent reduction (without manifolding)
§ 63.363 Compliance	
§ 63.363(a)	Initial performance test required within 180 days after CD
§ 63.363(b)	Determining compliance with SCV standard:

Table B-1. (continued)

Section in regulation	Contents or Requirement
§ 63.363(b)(1)	• Use test method in § 63.365(b)(1) to determine efficiency
§ 63.363(b)(1)(I)	•• Establish site-specific operating parameters for acid-water scrubbers ⇒ ethylene glycol concentration [EG] or scrubber liquor tank level
§ 63.363(b)(1)(ii)	•• Establish site-specific operating parameter for catalytic/thermal oxidizers ⇒ baseline temperature
§ 63.363(b)(2)	• Parameter violations
§ 63.363(c)	Determining compliance with ARV standard:
§ 63.363(c)(1)	• Use test method in § 63.365(c)(1) to determine EO concentration; use § 63.365(d)(1) to determine efficiency
§ 63.363(c)(2)	• Establish site-specific operating parameter for catalytic/thermal oxidizers ⇒ baseline temperature [T]
§ 63.363(c)(3)	• Parameter violations
§ 63.363(d)	Determining compliance with CEV standard for sources using ≥ 10 tons:
§ 63.363(d)(1)	• If manifolding to SCV or ARV, comply with those parameters
§ 63.363(d)(2)	• If using dedicated control device:
§ 63.363(d)(2)(I)	•• Use test method in § 63.365(d)(2) to determine efficiency; establish site-specific operating parameters for acid-water scrubbers ⇒ [EG] or scrubber liquor tank level; establish operating parameter for catalytic/thermal oxidizers ⇒ [T]
§ 63.363(d)(2)(ii)	•• Parameter violations
§ 63.363(e)	Determining compliance with CEV standard for sources using 1 to 10 tons:
§ 63.363(e)(1)	• If manifolding to SCV, comply with those parameters
§ 63.363(e)(2)	• If using dedicated control device:
§ 63.363(e)(2)(I)	•• Use test method in § 63.365(c)(2) to determine EO concentration [EO]
§ 63.363(e)(2)(ii)	•• Use test method in § 63.365(d)(2) to determine efficiency; establish site-specific operating parameters for acid-water scrubbers ⇒ [EG] or scrubber liquor tank level; establish operating parameter for catalytic/thermal oxidizers ⇒ [T]
§ 63.363(e)(3)	• Parameter violations
§ 63.363(f)	Compliance procedures for sources using other control devices

Table B-1. (continued)

Section in regulation	Contents or Requirement
§ 63.364 Monitoring	
§ 63.364(a)	Sources must comply with this section and subpart A
§ 63.364(b)	Acid-water scrubber monitoring:
§ 63.364(b)(1)	• [EG] - weekly
§ 63.364(b)(2)	• Scrubber liquor tank level - weekly
§ 63.364(c)	Catalytic/thermal oxidizer monitoring:
§ 63.364(c)(1)	• SCV ⇒ [T] over cycle length; average every third cycle
§ 63.364(c)(2)	• ARV ⇒ [T] over 1 hour; average every third hour
§ 63.364(c)(3)	• CEV ⇒ [T] over cycle length
§ 63.364(c)(4)	• Verify accuracy of [T] monitor every 6 months
§ 63.364(d)	Other control device monitoring according to § 63.365(g)
§ 63.364(e)	Monitoring of [EO]:
§ 63.364(e)(1)	• ARV - [EO] hourly; average every third hour; install gas chromatograph and calibrate daily
§ 63.364(e)(2)	• CEV (1 to 10 tons) - [EO] before chamber exhaust activation; install gas chromatograph and calibrate daily
§ 63.364(f)	If manifolding, comply with parameters for that device
§ 63.365 Test Methods and Procedures	
§ 63.365(a)	Sources subject to this section and subpart A
§ 63.365(b)	SCV - efficiency and parameter determination:
§ 63.365(b)(1)	• First evacuation of SCV - efficiency and parameter
§ 63.365(b)(2)	• Last evacuation of SCV - efficiency and parameter
§ 63.365(c)	Concentration determination for ARV and CEV (1 to 10 tons):
§ 63.365(c)(1)	• ARV - [EO]
§ 63.365(c)(2)	• CEV (1 to 10 tons) - [EO]
§ 63.365(d)	Efficiency and parameter determination for ARV and CEV:
§ 63.365(d)(1)	• ARV - efficiency
§ 63.365(d)(2)	• CEV (not manifolded)

Table B-1. (continued)

Section in regulation	Contents or Requirement
§ 63.365(e)	Parameter determination for acid-water scrubber:
§ 63.365(e)(1) § 63.365(e)(2)	• [EG] (any vent type) • Scrubber liquor tank level (any vent type)
§ 63.365(f)	Temperature determination for catalytic/thermal oxidizer:
§ 63.365(f)(1) § 63.365(f)(2) § 63.365(f)(3)	• SCV • ARV • CEV
§ 63.365(g)	Efficiency and parameter determination for other control devices
§ 63.365(h)	Alternative to gas chromatography for ARV or CEV standards
§ 63.366 Reporting	
§ 63.366(a)	Sources subject to this section and subpart A; content and submittal dates for summary, excess emissions, and monitoring system performance reports
§ 63.366(b)	Construction/reconstruction reporting
§ 63.366(c)	Notification reports
§ 63.367 Recordkeeping	
§ 63.367(a)	Sources subject to this section and subpart A
§ 63.367(b)	Sources using 1 to 10 tons maintain records of EO usage on 12-month rolling basis
§ 63.367(c)	Sources using < 1 ton maintain records of EO usage on 12-month rolling basis

APPENDIX C.
LIST OF KNOWN FACILITIES

Table C-1. List of Known Facilities

Facility name	Parent company	City	State
Travenol Laboratories, Inc.	American Hospital Supply	Mountain Home	AK
Alabama Dept. Of Agriculture		Montgomery	AL
Arkansas History Commission		Little Rock	AR
W.L. Gore & Assoc., Inc.		Flagstaff	AZ
Procter & Gamble		Phoenix	AZ
The Heard Museum		Phoenix	AZ
Botanicals International	Zuellig Botanicals, Inc.	Long Beach	CA
Cal-Compack Foods		Santa Ana	CA
Farmer Bros. Co.		Torrance	CA
Santa Maria Chili, Inc.		Santa Maria	CA
Allergan Pharmaceuticals		Irvine	CA
Maurry Biological Co., Inc.		Los Angeles	CA
Barnes Hind, Inc.		Sunnyvale	CA
Medlon, Inc.		Burbank	CA
Ways & Means, Inc.		San Rafael	CA
IVAC Corporation		San Diego	CA
American Bentley	American Hospital Supply	Irvine	CA
American Edwards Laboratories	American Hospital Supply	Irvine	CA
American Pharmaseal	American Hospital Supply	Irwindale	CA
Shiley, Inc.	Pfizer	Irvine	CA
3M		Goleta	CA
Abco Laboratories		Concord	CA
Micro-Biotrol, Inc.		Vernon	CA
Sterilization Services of Calif.		Anaheim	CA
Lowie Museum of Anthropology	University of California	Berkeley	CA
Telectronics		Englewood	CA
Cobe Laboratories		Lakewood	CO
Valleylab, Inc.	Pfizer	Boulder	CO

Table C-1. (continued)

Facility name	Parent company	City	State
Acme United Corp.		Stratford	CT
Becton, Dickinson & Company		Canaan	CT
Critikon, Inc.	Johnson & Johnson	Southington	CT
United States Surgical Corporation		North Haven	CT
Cryomedics, Inc.		Trumbull	CT
Davis & Geck, Inc.	American Cyanamid Company	Danbury	CT
Delaware Dept. Of Agriculture		Dover	DE
EI DuPont		Wilmington	DE
Cordis Corp.		Miami	FL
Critikon, Inc.	Johnson & Johnson	Tampa	FL
Sterile Design, Inc.		Tampa	FL
Seamless Hospital Products Co.		Ocala	FL
Steridyne Corp,.		Riviera Beach	FL
Kendall Company		Augusta	GA
C.R. Bard, Inc.		Covington	GA
Micro-Biotrol, Inc.		Smyrna	GA
Sterilization Services of Georgia		Atlanta	GA
Univ. Of Hawaii Hamilton Library		Honolulu	HI
Clinton Corn Processing Co.	ADM	Clinton	IA
Tone Brothers, Inc.		Des Moines	IA
Parks Library		Ames	IA
Abbott Laboratories		North Chicago	IL
Abbott Laboratories		North Chicago	IL
Travenol Laboratories, Inc.	American Hospital Supply	Round Lake	IL
Elgin Medical Corporation		Elgin	IL
Araclean Services, Inc.		LaGrange	IL
Micro-Biotrol, Inc.		Willowbrook	IL
Medsteril, Inc.		Mundelein	IL
Graham Center Archives	Wheaton College	Wheaton	IL

Table C-1. (continued)

Facility name	Parent company	City	State
Eli Lilly and Co.		Indianapolis	IN
Eli Lilly and Co.		Indianapolis	IN
Cook Inc.		Bloomington	IN
Reynier's Germfree Building		Notre Dame	IN
Kendall Company		Franklin	KY
Charles River Laboratories, Inc.		Wilmington	MA
Portex, Inc.		Wilmington	MA
C.R. Bard, Inc.		Billerica	MA
EI DuPont		Billerica	MA
Findley Research, Inc.		Fall River	MA
American Antiquarian Society		Worcester	MA
New Bedford Whaling Museum		New Bedford	MA
Conservation Lab	Old Sturbridge Village	Sturbridge	MA
First Church of Christ Scientist		Boston	MA
Maryland Dept. Of Agriculture		Annapolis	MD
Baltimore Spice	Durkee Foods	Garrison	MD
McCormick & Co., Inc.		Hunt Valley	MD
BBL Microbiology Systems	Becton Dickinson	Cockeysville	MD
Frederick Cancer Research Facility	NCI	Frederick	MD
The Jackson Laboratory		Bar Harbor	ME
Charles River Laboratories, Inc.		Portage	MI
General Spice, Inc.		Detroit	MI
Parke-Davis	Warner-Lambert Co.	Rochester	MI
The UpJohn Company		Kalamazoo	MI
Sarns, Inc.	3M Co.	Ann Arbor	MI
Tri-State Hospital Supply Corp.		Howell	MI
The UpJohn Company		Kalamazoo	MI
The UpJohn Company		Kalamazoo	MI
Medtronic, Inc. Rice Creek Facility	Medtronic, Inc.	Minneapolis	MN

Table C-1. (continued)

Facility name	Parent company	City	State
Daig Corporation		Minnetonka	MN
SciMed Life Systems, Inc.		Plymouth	MN
PRL	Medtronic, Inc.	Coon Rapids	MN
American Medical Systems, Inc.	Pfizer	Minnetonka	MN
A.D.T. Lab Industries, Inc.		Lakeville	MN
Spicecraft, Inc.		Gerald	MO
Hollister, Inc.		Kirksville	MO
Diagnostic Division	Mallinckrodt, Inc.	Maryland Hts	MO
Monsanto Company		St. Louis	MO
Midwest Sterilization Corp.		Cape Girardeau	MO
Flavorite Laboratories, Inc.		Horn Lake	MS
Travenol Laboratories, Inc.	American Hospital Supply	Cleveland	MS
NC Dept. Of Agriculture		Raleigh	NC
Charles River Laboratories, Inc.		Raleigh	NC
Abbott Laboratories		Laurinburg	NC
Abbott Laboratories		Rocky Mount	NC
Arrow International		Randleman	NC
Edward Weck and Company, Inc.		RTP	NC
IVAC Corporation		Creedmoor	NC
Baltimore Spice	Durkee Foods	Grand Forks	ND
Concord Laboratories, Inc.		Keene	NH
Millipore Corporation		Jaffrey	NH
Rutgers-Kilmer Facility	NJ Department of Agriculture	New Brunswick	NJ
Meer Corporation		North Bergen	NJ
American Hoechst Corporation		Somerville	NJ
E.R. Squibb & Sons	Squibb	North Brunswick	NJ
Leeming/Pacquin	Pfizer, Inc.	Parsippany	NJ
Squibb Corporation		Lawrenceville	NJ
C.R. Bard, Inc.		Murray Hill	NJ

Table C-1. (continued)

Facility name	Parent company	City	State
Vernitron Medical Products		Carlstadt	NJ
Ethicon, Inc.	Johnson & Johnson	Somerville	NJ
Johnson & Johnson Products, Inc.	Johnson & Johnson	New Brunswick	NJ
Johnson & Johnson Products, Inc.	Johnson & Johnson	New Brunswick	NJ
Johnson & Johnson Products, Inc.	Johnson & Johnson	New Brunswick	NJ
Overseas Spice Co.		Newark	NJ
Micro-Biotrol, Inc.		Boundbrook	NJ
ETO Sterilization, Inc.		Linden	NJ
N. Am. Sterilization & Package Co		Sparta	NJ
Pacon Manufacturing Corporation		South Planfield	NJ
Archives & History Center	United Methodist Church	Madison	NJ
Ethicon, Inc.	Johnson & Johnson	Albuquerque	NM
Baltimore Spice	Durkee Foods	Sparks	NV
Charles River Laboratories, Inc.		Kingston	NY
direrle Laboratories	American Cyanamid Company	Pearl River	NY
Bristol-Myers Company		East Syracuse	NY
G.C. Hanford Manufacturing Co.		Syracuse	NY
H.W. Andersen Products		Oyster Bay	NY
MCC Division	Mallinckrodt, Inc.	North Argyle	NY
Castle	Sybron Corp.	Rochester	NY
Deknatel Division	Pfizer Hospital Products Group	Queens Village	NY
Ethox Corp.		Buffalo	NY
Chesebrough-Pond's	Sherwood Medical Company	Sherburne	NY
Morris J. Golombeck, Inc.		Brooklyn	NY
Sterilization Tech. Services, Inc.		Rush	NY
Medical Sterilization, Inc.		Syosset	NY
Ben Venue Laboratories, Inc.		Bedford	OH
Medex, Inc.		Hilliard	OH
Dravon Medical, Inc.		Clackamas	OR

Table C-1. (continued)

Facility name	Parent company	City	State
Durkee Famous Foods	Durkee Foods	Bethlehem	PA
Merck Sharp & Dohme		West Point	PA
Sterling Drug, Inc.		Myerstown	PA
Wyeth Laboratories, Inc.		West Chester	PA
Wyeth Laboratories, Inc.		Marietta	PA
The West Co. Jersey Shore Facility		Jersey Shore	PA
Burron Medical, Inc.		Allentown	PA
Sharpoint, Inc.		Sinking Spring	PA
Araclean Services, Inc.		Scranton	PA
Squibb Manufacturing, Inc.		Humacao	PR
Lederle Parenteral, Inc.	American Cyanamid Company	Carolina	PR
Abbott Laboratories		Barceloneta	PR
Travenol Laboratories, Inc.	American Hospital Supply	Aguada	PR
Travenol Laboratories, Inc.	American Hospital Supply	Aibonito	PR
Travenol Laboratories, Inc.	American Hospital Supply	Jayuya	PR
Davis & Geck, Inc.	American Cyanamid Company	Manati	PR
Millipore Cidra, Inc.		Cidra	PR
MED REL, Inc.	Medtronic, Inc.	Humacao	PR
C.R. Bard, Inc.		Las Piedras	PR
American V. Mueller	American Hospital Supply	Anasco	PR
American Edwards Laboratories	American Hospital Supply	Anasco	PR
U.S. Surgical Corporation		Ponce	PR
Medtronic Puerto Rico, Inc.	Medtronic, Inc.	Villalba	PR
C.R. Bard, Inc.		Cranston	RI
Ethide Laboratories, Inc.		Coventry	RI
Travenol Laboratories, Inc.	American Hospital Supply	Kingstree	SC
Smith and Nephew		Columbia	SC
3M		Brookings	SD
Tennessee Dept. Of Agriculture		Nashville	TN

Table C-1. (continued)

Facility name	Parent company	City	State
American Pharmaseal	American Hospital Supply	Johnson City	TN
Sterilization Services of Tennessee		Memphis	TN
F ⌣ Pak Chili Company, Inc.		Fabens	TX
Baltimore Spice	Durkee Foods	Anthony	TX
Alcon Laboratories, Inc.		Forth Worth	TX
Sherwood Medical Company		Commerce	TX
Alva Medical	Mallinckrodt, Inc.	Angleton	TX
Argon Medical Corporation	Squibb	Athens	TX
U.S. Clinical Products, Inc.		Richardson	TX
Ethicon, Inc.	Johnson & Johnson	San Angelo	TX
Seamless Hospital Products Co.		El Paso	TX
Fort Belknap Archives, Inc.		Graham	TX
Permian Basin Petroleum Museum		Midland	TX
Abbott Laboratories		Salt Lake City	UT
Dept. of Ag & Consumer Services	Comonwealth of Virginia	Richmond	VA
Old Mansion, Inc.		Richmond	VA
Sterile Concepts, Inc.		Richmond	VA
Lukens Corporation		Lynchburg	VA
Gambro, Inc.		Newport News	VA
Crescent Foods		Seattle	WA
Action Medical Systems, Inc.		Kirkland	WA
Foran Spice Company		Oak Creek	WI
West Virginia Dept. Of Agriculture		Charleston	WV

TECHNICAL REPORT DATA

(Please read Instructions on reverse before completing)

1 REPORT NO	2	3 RECIPIENT'S ACCESSION NO
EPA 456/R-97-004		

4 TITLE AND SUBTITLE	5 REPORT DATE
Ethylene Oxide Commercial Sterilization and Fumigation Operations NESHAP Implementation Document	September 1997
	6 PERFORMING ORGANIZATION CODE

7 AUTHOR(S)	8 PERFORMING ORGANIZATION REPORT NO
David G. Hearne Susan J. Shrager	4203-31-02

9 PERFORMING ORGANIZATION NAME AND ADDRESS	10 PROGRAM ELEMENT NO
Midwest Research Institute 5520 Dillard Road, Suite 100 Cary, NC 27511	11 CONTRACT/GRANT NO 68-D3-0031, WA 31

12 SPONSORING AGENCY NAME AND ADDRESS	13 TYPE OF REPORT AND PERIOD COVERED
Office of Air Quality Planning and Standards Office of Air and Radiation U.S. Environmental Protection Agency Research Triangle Park, NC 27711	Final
	14 SPONSORING AGENCY CODE EPA/200/04

15 SUPPLEMENTARY NOTES

Project Officer is Gilbert Wood, Mail Drop 12, (919) 541-5272

16 ABSTRACT

National emissions standards to control emissions of HAP from new and existing ethylene oxide commercial sterilization and fumigation operations were promulgated in 1994. This document contains information to assist State and local air pollution control agencies as well as the regulated community in the implementation of these standards. This document provides a common sense summary of the NESHAP requirements, describes the most frequently encountered emissions points, and describes the most commonly used emissions control devices. Sample inspection sheets are also provided as is a bibliography of Federal, State and private sources of additional information related to these standards.

17 KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
Air pollution Air pollution control National emissions standards Hazardous air pollutants Ethylene oxide Commercial sterilization and fumigation industry Implementation guidance	Air pollution control Ethylene oxide Stationary sources	13B

18 DISTRIBUTION STATEMENT	19 SECURITY CLASS *(Report)*	21 NO OF PAGES
Unlimited	Unclassified	70
	20 SECURITY CLASS *(Page)*	22 PRICE
	Unclassified	

EPA Form 2220-1 (Rev. 4-77) PREVIOUS EDITION IS OBSOLETE

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

STERIGENICS U.S., LLC,	)	
	)	
Plaintiff,	)	
	)	**No. 19 C 1219**
v.	)	
	)	**Chief Judge Rubén Castillo**
JOHN KIM et al.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Sterigenics U.S., LLC ("Plaintiff") brings this action against the Illinois Environmental Protection Agency ("IEPA") and John Kim ("Kim") in his capacity as acting director of IEPA (collectively, "Defendants"). (R. 54, Am. Compl. ¶¶ 1-7.) Plaintiff operates a sterilization facility in Willowbrook, Illinois, where it stores ethylene oxide, a chemical substance used to sterilize medical devices. (*Id.* ¶ 5.) Plaintiff alleges that Defendants overstepped their authority under Illinois law and deprived it of procedural due process under the U.S. Constitution when Defendants issued a "seal order" that required Plaintiff to seal all storage containers of ethylene oxide at the Willowbrook facility. (*Id.* ¶¶ 1-4, 38-63.) Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), Defendants move to dismiss Plaintiff's lawsuit for lack of subject-matter jurisdiction and failure to state a claim. (R. 63, Mot. at 1-2.) Defendants' motion is granted for the reasons stated below.

BACKGROUND

Plaintiff is a limited liability company with its principal place of business in Broadview Heights, Ohio, that provides commercial sterilization services for companies in the healthcare and food industries. (R. 54, Am. Compl. ¶ 5.) Plaintiff operates a sterilization facility in

Willowbrook that, on a typical day, sterilizes approximately 1,000 medical devices used in heart surgery, 1,000 knee implants, 1,500 surgical kits, 16,000 catheters, 11,000 syringes, thousands of diabetes monitoring and care kits, and many other medical products. (*Id.*) Plaintiff or its predecessors have operated this facility continuously since 1984, and the facility has allegedly been operating pursuant to permit number 95120085 issued by IEPA under the U.S. Environmental Protection Agency's ("EPA") Clean Air Act Permit Program. (*Id.* ¶¶ 11-12.) Plaintiff alleges that it has consistently emitted "far less ethylene oxide than its permit allows," and that it has "voluntarily improved its safety measures for ethylene oxide well beyond what the law requires." (*Id.* ¶¶ 14-15.) Plaintiff also claims that the Willowbrook facility is not currently in violation of any rules or regulations promulgated by EPA or IEPA, and that its operating permits have not been modified, terminated, or revoked. (*Id.* ¶¶ 17-18.)

On February 15, 2019, Defendants issued a seal order, which sealed "[a]ll storage containers of ethylene oxide" at Plaintiff's Willowbrook facility pursuant to 415 ILL. COMP. STAT. 5/34(b), a statutory provision in Illinois' Environmental Protection Act (the "Act") that Plaintiff claims only applies if an emergency exists or if there is imminent and substantial endangerment to the public health, welfare, or environment. (*Id.* ¶¶ 1-2.) Plaintiff alleges that, instead of seeking relief through the court system or regulatory process, "Defendants decided to bypass the court system . . . to 'sandbag' [Plaintiff]" by issuing the seal order. (*Id.* ¶ 22.) Plaintiff claims that at no point before or on the date the seal order was issued, did the IEPA or EPA represent that the Willowbrook facility's use and storage of ethylene oxide posed a safety concern or emergency. (*Id.* ¶ 23.) Plaintiff alleges that the seal order justifies itself by citing a questionable August 2018 report regarding the Willowbrook facility's ethylene oxide emissions,

and that the EPA sent letters to Illinois officials stating that the Willowbrook facility was not causing immediate harm to persons in and around Willowbrook. (*Id.* ¶¶ 25-29, 31.)

Plaintiff has allegedly attempted to reach out to IEPA to determine what measures it can take to have the seal order lifted and continue sterilization activities in Willowbrook, but Plaintiff claims that Defendants have not cooperated. (*Id.* ¶ 33.) Plaintiff alleges that the seal order has caused serious harm to Plaintiff, Plaintiff's customers, and the United States' healthcare system at large. (*Id.* ¶ 35.) According to Plaintiff, the closure of the Willowbrook facility impacts several medical device companies and "risks creating [medical] device shortages with serious adverse effects on healthcare in this country." (*Id.* ¶¶ 36-37.)

PROCEDURAL HISTORY

On October 30, 2018, the state of Illinois filed a lawsuit against Plaintiff in Illinois state court. (*Id.* ¶ 19.) Plaintiff removed the case to this District where the case was assigned to U.S. District Judge John Lee. (*Id.*) Plaintiff alleges that the October 2018 lawsuit seeks the same relief as the seal order, but none of the relief in that case was pursued on an emergency basis or claimed to be necessary to resolve an "imminent and substantial endangerment" to the public health, welfare, or environment. (*Id.*) On March 11, 2019, Judge Lee remanded the October 2018 lawsuit back to state court. (18-cv-8010, R. 48, Order at 16.)

Judge Lee reasoned there was no subject-matter jurisdiction to proceed in federal court and thus rejected Plaintiff's contention that the State brought a federal cause of action sufficient to establish federal question jurisdiction. (*Id.* at 7-13.) Specifically, Judge Lee reasoned that the lawsuit did not involve a suit by the State against Plaintiff for failure to comply with the Clean Air Act, 42 U.S.C. §§ 7401, *et seq.*, or any other federal statute that might raise a federal question, but instead was a suit to enjoin Plaintiff "*despite* its compliance with the [Clean Air

Act][.]" (*Id.* at 9-10.) As a result, Judge Lee concluded that the lawsuit was one involving only state law causes of action, and that Illinois' state laws and regulations implementing the Clean Air Act were not claims arising under federal law that could provide a basis for subject-matter jurisdiction. (*Id.* at 10-15.)

Approximately a month before Judge Lee remanded the October 2018 action, on February 18, 2019, Plaintiff filed its initial complaint in this case, which brought a claim under 42 U.S.C. § 1983 for deprivation of its procedural due process rights under the Fifth and Fourteenth Amendments and a claim alleging that Defendants violated Section 34(b) of the Act. (R. 1, Compl. ¶¶ 24-34.) The same day Plaintiff filed its complaint, it also filed a motion for a preliminary injunction and temporary restraining order ("TRO"). (R. 5, Mot.) The motion for a TRO was heard on February 20, 2019, by U.S. District Judge Matthew Kennelly who was the designated emergency judge at the time. (R. 28, Min. Entry.)

Judge Kennelly denied Plaintiff's motion for a TRO and reasoned that Plaintiff did not have a reasonable likelihood of success on the merits. (R. 51-1, Tr. at 74.) Judge Kennelly relied on the U.S. Supreme Court's decision in *Hodel v. Virginia Surface Mining & Reclamation Ass'n, Inc.*, 452 U.S. 264, 298-305 (1981), in which the Supreme Court ruled that a state statute did not violate constitutional rights to due process although it allowed a state agency to order, without a hearing beforehand, a cessation of surface mining if necessary to protect public health or safety so long as a hearing or process occurred after the issuance of the cessation order. (*Id.* at 74-76.) Judge Kennelly reasoned further that the controlling inquiry was whether Section 34(b) of the Act is incapable of providing due process and not whether Defendants had authority under the Act to issue the seal order. (*Id.* 75-76.) Judge Kennelly concluded that because the Act provides for due process after Defendants issued the seal order, Plaintiff has little chance of succeeding on

the merits of its due process claims. (*Id.*) Judge Kennelly also found that Plaintiff's lawsuit did not have a reasonable likelihood of success on the merits because it essentially asks a federal court to order a state official to comply with state law and therefore is likely barred by the Eleventh Amendment. (*Id.* at 76-77.) Accordingly, Judge Kennelly denied the TRO. (*Id.* at 77.)

On February 27, 2019, the case was reassigned to this Court. (R. 38, Order.) Subsequently, on March 7, 2019, Plaintiff filed an amended complaint. (R. 54, Am. Compl.) The amended complaint brings three counts against Defendants. (R. 54, Am. Compl. ¶¶ 38-63.) The first two counts bring claims under 42 U.S.C. § 1983 for a deprivation of Plaintiff's procedural due process rights under the Fifth and Fourteenth Amendments based on Defendants' alleged failure to provide a hearing or other adequate process to challenge the issuance of the February 15 seal order before or after Defendants issued the seal order. (*Id.* ¶¶ 38-57.) The third count alleges that the seal order is an unlawful use of Defendants' authority under Section 34(b) of the Act. (*Id.* ¶¶ 58-63.)

Defendants move to dismiss the amended complaint, (R. 63, Mot.), first arguing that Plaintiff fails to plausibly allege that Defendants deprived Plaintiff of its constitutional right to a hearing or other process to challenge the seal order before or after it was issued. (R. 64, Mem. at 6-12.) Defendants maintain that the Constitution allows them to deprive Plaintiff of its property without a pre-deprivation hearing in situations where "swift action is necessary to protect the public health and safety." (*Id.* at 8.) Defendants also argue that a pre-deprivation due process claim only arises if the Act is incapable of affording due process; therefore, according to Defendants, Plaintiff's claim fails because the Act does afford due process. (*Id.* at 9-10.)

With respect to Plaintiff's claim that it was deprived of due process after the seal order was issued, Defendants again argue that the Act affords adequate process and therefore the Court

should dismiss Plaintiff's post-deprivation due process claim. (*Id.* at 10-11.) Defendants also argue that the seal order itself outlines what Plaintiff can do to have the seal order lifted, and that Plaintiff adopts an untenable position that would require Defendants to provide detailed instructions regarding the steps Plaintiff must take before the seal order is lifted. (*Id.* at 11-12.)

According to Defendants, because there is no viable federal claim, the Court should dismiss Plaintiff's state law claim because the Court is left with no independent grounds for subject-matter jurisdiction. (*Id.* at 12-13.) Defendant also maintains that, in addition to Plaintiff's failure to state a federal claim giving rise to federal jurisdiction, Plaintiff's lawsuit is barred by the Eleventh Amendment because it asks the Court to order state officials to comply with state law. (*Id.* at 13-15.) Lastly, Defendants argue that, pursuant to *Younger v. Harris*, 401 U.S. 37 (1971), the Court should abstain from exercising jurisdiction over this case because it involves an ongoing state administrative enforcement proceeding. (*Id.* at 15-16.)

In response, Plaintiff argues that it has adequately alleged a deprivation of its procedural due process rights. (R. 72, Resp. at 5-12.) Plaintiff also maintains that it has sufficiently pleaded a violation of due process because it has alleged that Defendants issued a facially valid permit to operate the Willowbrook facility and then deprived Plaintiff of that permit without providing notice of the permit's invalidity. (*Id.* at 8-11.) According to Plaintiff, controlling legal authorities forbid such "regulation by ambush." (*Id.* at 9.) Plaintiff also contends that its lawsuit is not barred by the Eleventh Amendment, and that the abstention doctrine from *Younger* does not apply. (*Id.* at 12-15.) Defendants' motion to dismiss is fully briefed and ripe for the Court's consideration. (R. 75, Reply.)

LEGAL STANDARDS

A complaint must set forth a "short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). "A motion to dismiss pursuant to Rule 12(b)(6) challenges the viability of a complaint by arguing that it fails to state a claim upon which relief may be granted." *Firestone Fin. Corp. v. Meyer*, 796 F.3d 822, 825 (7th Cir. 2015) (quotation and internal alteration omitted); *see also* FED. R. CIV. P. 12(b)(6). "Although detailed factual allegations are unnecessary, the complaint must have 'enough facts to state a claim to relief that is plausible on its face.'" *Pierce v. Zoetis, Inc.*, 818 F.3d 274, 277 (7th Cir. 2016) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. "To rise above the speculative level of plausibility, the complaint must make more than threadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Oakland Police & Fire Ret. Sys. v. Mayer Brown, LLP*, 861 F.3d 644, 649 (7th Cir. 2017) (quotation and alteration omitted). In deciding a motion to dismiss, however, the Court accepts the factual allegations in the complaint as true and draws all reasonable inferences in favor of the plaintiff. *Kanter v. Barr*, 919 F.3d 437, 441 (7th Cir. 2019).

Plaintiff also moves to dismiss pursuant to Rule 12(b)(1). (R. 63, Mot. at 1-2.) A motion to dismiss pursuant to Rule 12(b)(1) challenges this Court's subject-matter jurisdiction over the action. FED. R. CIV. P. 12(b)(1). Defendants' Rule 12(b)(1) motion is a facial challenge to subject-matter jurisdiction because it contends that Plaintiff's amended complaint lacks sufficient

factual allegations to establish jurisdiction. *See Silha v. ACT, Inc.*, 807 F.3d 169, 173 (7th Cir. 2015). The Court reviews a facial challenge to subject-matter jurisdiction under the same standard set forth above for a motion to dismiss for failure to state a claim. *Id.* at 173-74. Thus, the Court determines whether Plaintiff's well-pleaded allegations plausibly suggest a basis for subject-matter jurisdiction. *Id.*

ANALYSIS

I. The Eleventh Amendment

The Court first addresses Defendants' argument that the Court lacks subject-matter jurisdiction over this lawsuit because it is barred by the Eleventh Amendment, (R. 64, Mem. at 13-15). The Eleventh Amendment provides that "[t]he Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State." U.S. CONST. AMEND. XI. Courts have construed this language broadly to confer sovereign immunity upon the states, which "guarantees that an unconsenting State is immune from suits brought in federal courts by her own citizens as well as by citizens of another State." *Council 31 of the Am. Fed'n of State, Cty. & Mun. Emps., AFL-CIO v. Quinn*, 680 F.3d 875, 881 (7th Cir. 2012) (quotations omitted). The Eleventh Amendment, therefore, bars private individuals from suing a state or state officials acting in their official capacities in federal court without the state's consent. *Mutter v. Rodriguez*, 700 F. App'x 528, 530 (7th Cir. 2017); *see also Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 121 (1984) ("A claim that state officials violated state law in carrying out their official responsibilities is a claim against the State that is protected by the Eleventh Amendment."). "Obligations of public bodies under state law should be determined by state courts unless there is a very good reason why the federal court should intervene." *Shegog v. Bd. of Educ. of City of Chi.*, 194 F.3d 836, 839 (7th Cir. 1999). Consequently, "[h]ow

far state law exposes state and local agencies to liability is a delicate question that federal judges should hesitate to tackle." *Myers v. Cty. of Lake*, 30 F.3d 847, 849 (7th Cir. 1994).

There are, however, exceptions to the Eleventh Amendment's reach. One exception set forth by the Supreme Court in *Ex parte Young*, 209 U.S. 123, 159-60 (1908), applies to suits against state officials in their official capacities to require their compliance with federal law on an ongoing basis. *McDonough Assocs., Inc. v. Grunloh*, 722 F.3d 1043, 1049 (7th Cir. 2013); *see also Ex parte Young*, 209 U.S. at 155-56, 160. Plaintiff argues that this lawsuit falls within the *Ex parte Young* exception because it asks the Court to order state officials to prospectively comply with federal law. (R. 72, Resp. at 13-15.)

In determining whether the doctrine of *Ex parte Young* applies, "a court need only conduct a straightforward inquiry into whether the complaint alleges an ongoing violation of federal law and seeks relief properly characterized as prospective." *McDonough Assocs.*, 722 F.3d at 1051 (internal quotation marks and alterations omitted); *Council 31*, 680 F.3d at 882. Plaintiff fails the first part of this inquiry because it only alleges a violation of state law.

Plaintiff's allegations are analogous to those in *Tenny v. Blagojevich*, 659 F.3d 578 (7th Cir. 2011), a case where the court concluded that the plaintiffs' due process claims were barred by the Eleventh Amendment. In *Tenny*, inmates alleged that state officials marked up the prices above the Illinois statutory limit for goods purchased from prison commissaries. *Tenny*, 659 F.3d at 579-80. The inmates claimed that they were deprived of procedural due process because they never had an opportunity to challenge the marked-up prices before the prices took effect, but the court concluded that the due process claims were barred by the Eleventh Amendment because the allegations were "about *what* was done (the mark-up in excess of 25%), not the *procedures* followed to do it." *Id.* at 582-83. Thus, the court reasoned that the constitutional due process

claims essentially complained of a state violating state law and were barred by the Eleventh Amendment. *Id.* at 583.

Like *Tenny*, Plaintiff's allegations are directed toward what Defendants did, namely, invoking Section 34(b) allegedly without any emergency or imminent and substantial endangerment to public health that would justify action under Section 34(b). (*See, e.g.*, R. 54, Am. Compl. ¶ 41.) Specifically, Plaintiff alleges that Defendants issued the seal order without any explanation, any true emergency situation at the Willowbrook facility, and without affording Plaintiff the ability to address any emergency situation and lift the seal order in a manner other than resorting to litigation in the courts. (*Id.* ¶¶ 38-57.) The crux of these allegations is that Defendants violated state law to bypass the regulatory process and courts. (*Id.* ¶¶ 3, 22.) As a result, Plaintiff's lawsuit merely recasts a state-law claim seeking injunctive relief for violation of Section 34(b) as constitutional due process claims. (*See id.* ¶¶ 58-63.) Although Plaintiff labels its claims as procedural due process claims, the Eleventh Amendment prohibits this Court from ordering Defendants to comply with Section 34(b). *See Tenny*, 659 F.3d at 583; *Sutherland v. Leonhart*, No. 11-CV-4663, 2012 WL 1886442, at *3 (N.D. Ill. May 23, 2012) (dismissing complaint where the plaintiff, at bottom, alleged that a state failed to fulfill its duties under state law); *Price v. Ill. Dep't of Ins.*, No. 12 C 6959, 2013 WL 535563, at *2 (N.D. Ill. Feb. 12, 2013) ("[T]o the extent that [the plaintiff] accuses [a state official] of failing to properly apply Illinois law governing the issuance of insurance licenses, this court lacks jurisdiction to consider his claims.").

The Court, as a result, rejects Plaintiff's argument that its claims fall within the *Ex Parte Young* exception, which applies to claims involving violations of federal law, not state law. *See McDonough Assocs., Inc.*, 722 F.3d at 1051. The Court also rejects Plaintiff's argument that its

claim against Defendants under Section 34(b) of the Act is a violation of federal law that does not trigger any Eleventh Amendment concerns.[1] (*See* R. 72, Resp. at 14-15.) Section 34 is a provision of a state statute, and Plaintiff's lawsuit brings a cause of action under this state statute, which allows Plaintiff to challenge the seal order in a lawsuit seeking injunctive relief. 415 ILL. COMP. STAT. 5/34(d); *see also Chi. Tribune Co. v. Bd. of Trs. of Univ. of Ill.*, 680 F.3d 1001, 1002-03 (7th Cir. 2012) (focusing on, for purposes of whether a claim is barred by the Eleventh Amendment, whether the claim "arises under Illinois law").

Plaintiff refers to Section 34 in its complaint and does not bring this action pursuant to the federal Clean Air Act. Nor can Plaintiff bring a lawsuit under the Clean Air Act to enjoin the seal order because the Clean Air Act only allows a private party like Plaintiff to sue to enforce emissions standards imposed by the Clean Air Act. *See* 42 U.S.C. § 7604(a)(3). Accordingly, because Plaintiff brings state law claims and invokes state law remedies to force Defendants to comply with state law, the Eleventh Amendment bars this Court from adjudicating Plaintiff's claims. *See Jones v. Indiana*, 533 F. App'x 672, 673 (7th Cir. 2013) ("The Eleventh Amendment to the Constitution *prevents federal courts from awarding relief, under state law*, against states and their agencies." (emphasis added)); *James*, 373 F. App'x at 621 (observing, in a case where the plaintiff based his claim on a state statute, that although *Ex parte Young* "permits prospective relief against a state official to ensure future compliance with federal law, this approach does not apply to claims under state law").

Plaintiff argues that its claims under Section 34(b) allege a violation of federal law because Section 34(b) is part of Illinois' State Implementation Plan ("SIP") under the federal

[1] Notably, Plaintiff essentially conceded during argument on its motion for a TRO that its Section 34 claim is a state law claim. (R. 51-1, Tr. at 73 (Plaintiff's counsel stating that "we would have a problem" under the Eleventh Amendment if the only claim brought was Plaintiff's Section 34 claim).)

Clean Air Act that the EPA must approve. (R. 72, Resp. at 14.) Plaintiff contends that once the SIP is approved by the EPA, "a state rule embodied in a SIP becomes enforceable federal law." (*Id.* (quoting *Indiana v. U.S. Envtl. Prot. Agency*, 796 F.3d 803, 806 (7th Cir. 2015).) That the federal government and state government work together to enforce environmental laws does not change the Court's conclusion that the Eleventh Amendment bars Plaintiff from pursuing this lawsuit in federal court. The U.S. Court of Appeals for the Seventh Circuit has rejected an argument similar to Plaintiff's in a case where the plaintiff invoked the Act in federal court to challenge an IEPA decision. *E.g.*, *EOR Energy LLC v. Ill. Envtl. Prot. Agency*, 913 F.3d 660, 664 (7th Cir. 2019) (affirming dismissal of claim that IEPA did not have jurisdiction to regulate the plaintiff's acid dumping and concluding that the suit was barred by the Eleventh Amendment "[a]lthough the enforcement of environmental laws is in part accomplished through a partnership between the states and the federal government"); *see also Union Oil Co. of Cal. v. Leavell*, 220 F.3d 562, 566 (7th Cir. 2000) (observing that Illinois regulatory agency "should have been dismissed immediately" from a lawsuit related to the agency's actions because the Eleventh Amendment barred the claim against the agency to the extent it relied on state law).

Additionally, the legal principle and supporting case law that Plaintiff relies on stand for the simple proposition that the federal government can enforce SIP rules. *Indiana*, 796 F.3d at 806; *Gen. Motors Corp. v. United States*, 496 U.S. 530, 540 (1990) ("The language of the Clean Air Act plainly states that EPA may bring an action for penalties or injunctive relief whenever a person is in violation of any requirement of an 'applicable implementation plan.'"). They do not address Eleventh Amendment concerns or stand for the broader proposition that claims invoking a state's environmental protection statute and state remedies also allege violations of federal law

or claims arising under federal law. *See Indiana*, 796 F.3d at 806; *Gen. Motors Corp.*, 496 U.S. at 540.

Plaintiff also contends that under "Judge Lee's reasoning" for remanding the October 2018 action to state court due to a lack of subject-matter jurisdiction, Plaintiff's claim for a violation of Section 34(b) alleges a violation of federal law. (R. 72, Resp. at 15.) The Court disagrees. Judge Lee only reasoned that federal question jurisdiction might exist "*if the State were suing* [Plaintiff] for failing to meet its . . . permit obligations, and thus, national air quality standards." (18-cv-8010, R. 48, Order at 9-13 (emphasis added).) That is not the situation here; rather, *Plaintiff is suing* the State for allegedly acting outside of its authority under Illinois' SIP. (*See* R. 72, Resp. at 15.) As Judge Lee noted in his decision, the parties' dispute concerns Defendants' desire to stop Plaintiff's emissions of ethylene oxide at the Willowbrook facility "*despite* its compliance with the [Clean Air Act] and the SIP." (18-cv-8010, R. 48, Order at 9-10.) Like the dispute before Judge Lee, Plaintiff alleges it complies with all regulatory requirements, but Defendants nonetheless issued a seal order requiring Plaintiff to seal all ethylene oxide containers at the Willowbrook facility. (R. 54, Am. Compl. ¶¶ 2-3, 14, 17-18, 22-34.) Thus, Plaintiff's suit implicates state, not federal, law. (*See* 18-cv-8010, R. 48, Order at 9-13.) Accordingly, this lawsuit is dismissed without prejudice to Plaintiff pursuing its claims in state court. *See Lewert v. P.F. Chang's China Bistro, Inc.*, 819 F.3d 963, 969 (7th Cir. 2016) (dismissal for lack of subject-matter jurisdiction is a dismissal without prejudice).

II. Procedural Due Process Claims

Even if sovereign immunity did not bar Plaintiff's lawsuit, the suit would nevertheless be dismissed for failure to state any federal claim giving rise to federal jurisdiction. *See* 28 U.S.C. § 1331. Section 1983 creates a federal cause of action against any person who, under color of state law, subjects, or causes to be subjected, any citizen of the United States "to the deprivation

of any rights, privileges, or immunities secured by the Constitution[.]" 42 U.S.C. § 1983. Plaintiff alleges that Defendants deprived it of its due process under the Fifth or Fourteenth Amendment by issuing the seal order without a hearing or other process and because there is no adequate process for Plaintiff to lift the seal order. (R. 54, Am. Compl. ¶¶ 38-57.)

"The Due Process Clause of the Fifth and Fourteenth Amendments prohibits deprivation of life, liberty, and property without due process of law." *Mann v. Vogel*, 707 F.3d 872, 877 (7th Cir. 2013) (quotation omitted). "A procedural due process claim under § 1983 requires that the plaintiff allege (1) deprivation of a protected interest, and (2) insufficient procedural protections surrounding that deprivation." *Cannici v. Vill. of Melrose Park*, 885 F.3d 476, 479 (7th Cir. 2018) (quotation omitted). Therefore, "[a] procedural due process claim involves a two-step analysis: First, [the Court] determine[s] whether the defendants deprived the plaintiff of a protected liberty or property interest, and if so, then [the Court] assess[es] what process was due." *Abcarian v. McDonald*, 617 F.3d 931, 941 (7th Cir. 2010) (quotation omitted). The parties do not dispute that the seal order deprives Plaintiff of a property interest, (R. 72, Resp. at 5; R. 75, Reply at 1-9), so the Court focuses on what process was due to Plaintiff.

In evaluating what satisfies due process under the Constitution, "the Supreme Court has distinguished between (a) claims based on established state procedures and (b) claims based on random, unauthorized acts by state employees." *Leavell v. Ill. Dep't of Nat. Res.*, 600 F.3d 798, 804 (7th Cir. 2010). "A claim based on a deprivation from established state procedures requires more than simply the availability of post-deprivation procedures." *Cannici*, 885 F.3d at 479. "The state's ability to predict when a deprivation will occur provides the state the ability to provide a pre-deprivation hearing." *Id.* "By contrast, when the state conduct in question is random and unauthorized, the state satisfies procedural due process requirements so long as it

provides a meaningful post-deprivation remedy." *Leavell*, 600 F.3d at 805 (quotation omitted). Thus, "for a plaintiff alleging a procedural due process claim based on 'random and unauthorized' conduct of a state actor, the plaintiff must either avail herself of state post-deprivation remedies or demonstrate that the available remedies are inadequate." *Id.* (quotation omitted).

Plaintiff alleges that the seal order seeks "to circumvent both regulatory and judicial processes," and that it is an "extra-legal attempt to accomplish instantaneously what it cannot lawfully do without proper notice and process." (R. 54, Am. Compl. ¶ 3.) Plaintiff alleges further that, with the seal order, "Defendants decided to bypass the court system" and pending court action in which Defendants allegedly sought the same relief they achieved through the seal order. (*Id.* ¶ 22.) Plaintiff claims that the seal order was justified by an August 2018 report issued by the "Agency for Toxic Substances and Disease Registry," who "is not a regulator" issuing reports that have "the force of law." (*Id.* ¶ 24.) According to Plaintiff, Defendants' justification for the seal order is contrary to the EPA's conclusions regarding the health risks posed by Plaintiff's Willowbrook facility, and that Plaintiff has operated the Willowbrook facility with IEPA's authorization and in compliance with all applicable regulations. (*Id.* ¶¶ 23, 25-26, 31, 41, 47.) These allegations essentially allege that Defendants violated Section 34(b) of the Act by issuing a seal order in the absence of an emergency. Plaintiff's due process claims fail at the outset because a state government does not violate the federal constitution just because it violates a state law. *Daw v. Consol. City of Indianapolis & Marion Cty.*, 734 F. App'x 357, 358-59 (7th Cir. 2018); *Bradley v. Sabree*, 594 F. App'x 881, 883 (7th Cir. 2015).

Additionally, Plaintiff's allegations detail "random and unauthorized" misconduct by IEPA officials in which they issued a seal order outside of established administrative and court

procedures in an effort to bypass those procedures. *See Cannici*, 885 F.3d at 480 (noting that "unpredictable misconduct" based on a failure to follow requirements of existing law is a "random and unauthorized" act); *Dufour v. Matrisch*, No. 18 CV 1269, 2018 WL 4073337, at *4 n.4 (N.D. Ill. Aug. 27, 2018) (finding that the plaintiff alleged a "random and unauthorized act" because he alleged that an Illinois regulatory commission overrode another official's "issuance of [the plaintiff's] permit by revoking it, suggesting that the [regulatory commission's] employees were not following established procedures but rather acting in a 'random and unauthorized' way"); *cf. Bolton v. Bryant*, 71 F. Supp. 3d 802, 810 (N.D. Ill. 2014) ("When a state official acts within the bounds of discretion given to him by law, his acts are not random and unauthorized."). In such circumstances involving alleged random and unauthorized misconduct, no pre-deprivation process is required. *See Armstrong v. Daily*, 786 F.3d 529, 545 (7th Cir. 2015) (observing that, in the case of "random and unauthorized" state actions, "no pre-deprivation hearing is required because it would be utterly impractical"); *Freelain v. Vill. of Oak Park*, No. 17 C 6592, 2018 WL 1635853, at *6 (N.D. Ill. Apr. 5, 2018) (dismissing pre-deprivation procedural due process claim based on allegedly "random and unauthorized" acts). Accordingly, Plaintiff fails to allege any plausible grounds to support its pre-deprivation due process claim.

Plaintiff relies heavily on *Simpson v. Brown County*, 860 F.3d 1001 (7th Cir. 2017), but that case is distinguishable. *Simpson* involved allegations that a county board revoked the plaintiff's license to install and repair septic systems without prior notice or an opportunity to be heard. *Simpson*, 860 F.3d at 1003. The court in *Simpson* concluded that the plaintiff had alleged a "septic ordinance that plainly described the process for the placement of septic installers on a register and . . . described the process for their removal[;]" therefore, the plaintiff had sufficiently

alleged that when the county officer revoked the plaintiff's license, the officer "acted pursuant to his broadly delegated powers derived from the ordinance." *Id.* at 1008. The court reasoned that "any license revocation that is 'random and authorized' will be an aberration" because the "existence of a license or permit implies the existence of a legal framework with revocation guidelines." *Id.* at 1007.

This case, on the other hand, does not involve Plaintiff's license to operate but a seal order that Plaintiff alleges is a circumvention of "regulatory and judicial processes" and an "extra-legal attempt to accomplish instantaneously what [Defendants] cannot lawfully do without proper notice and process." (R. 54, Am. Compl. ¶ 3.) *Simpson*, therefore, is not analogous because the plaintiff there alleged an established state procedure and broad delegation of power that led to the plaintiff's loss of a property interest. *Simpson*, 860 F.3d at 1007-10. There are no such allegations here and instead only allegations of state officials acting outside of their authority and in violation of state law. (R. 54, Am. Compl. ¶¶ 3, 22-47.)

Plaintiff's cited authorities outside of the Seventh Circuit are not binding on this Court and are nonetheless unpersuasive. They are either inapposite cases weighing evidence instead of allegations or involve situations where the state's actions depriving a person of due process was predictable and alleged to be part of an established state procedure, unlike the allegations in this case. (*See* R. 72, Resp. at 6-7 (citing *RBIII, L.P. v. City of San Antonio*, 713 F.3d 840, 847 (5th Cir. 2013); *Elsmere Park Club, L.P. v. Town of Elsmere*, 542 F.3d 412, 418 (3d Cir. 2008); *Catanzaro v. Weiden*, 188 F.3d 56, 62 (2d Cir. 1999); *Armendariz v. Penman*, 31 F.3d 860, 866 (9th Cir. 1994), *vacated in part on reh'g en banc*, 75 F.3d 1311 (9th Cir. 1996).) As a result, the Court concludes that Plaintiff fails to allege a pre-deprivation procedural due process claim because Plaintiff only alleges "random and unauthorized" acts by state officials for which no

pre-deprivation process is required. *See Armstrong*, 786 F.3d at 545; *Freelain*, 2018 WL 1635853, at *6.

Plaintiff then contends that the fair notice principles of due process prohibit Defendants from issuing a seal order because IEPA has approved of the Willowbrook facility's operation through the state's permitting process. (R. 72, Resp. at 8-11.) Plaintiff relies on *Wisconsin Resources Protection Council v. Flambeau Mining Co.*, 727 F.3d 700 (7th Cir. 2013), a case in which private citizens sued a mining company pursuant to the citizen-suit provisions of the Clean Water Act, 33 U.S.C. §§ 1251 *et seq.* (R. 72, Resp. at 8-9.) *Flambeau*, however, is not analogous. It addressed a due process claim that the defendant did not have fair notice of the type of permit it needed under the Clean Water Act to discharge storm water into a Wisconsin river. *Flambeau Mining Co.*, 727 F.3d at 708-09. The court reasoned that a "private party is entitled to rely on published regulations," and that "a defendant could not be charged," for example, "with violating the Clean Air Act when it complied with the published version of a regulation that was part of [a state's] administration of the Clean Air Act." *Id.* at 709. Thus, the court ruled that the plaintiffs could not hold the defendant liable for lacking a particular permit because it had the permit that state regulators told defendant was adequate, and the Clean Water Act shields a party from liability if it operates pursuant to a facially valid permit so long as the party was not on notice that its permit was invalid. *Id.* at 710-11.

Flambeau thus addressed an established state procedure, unlike the random and unauthorized conduct Plaintiff alleges in this case that was an attempt "to circumvent . . . regulatory and judicial processes." (R. 54, Am. Compl. ¶ 3.) Accordingly, *Flambeau* does not alter the Court's conclusion.

Additionally, *Flambeau* is a fair notice case that has no application here because Plaintiff's pre-deprivation due process claims are based on a deprivation of its property rights "without conducting any pre-deprivation hearing" or providing Plaintiff with "the opportunity to be heard at a meaningful time in a meaningful manner." (R. 54, Am. Compl. ¶¶ 38-49.) Plaintiff's due process claims are not—and could not be—based on allegations of a lack of fair notice of Section 34(b) under the Act or Defendants' authority under Section 34(b), a statutory provision that has been codified for years. *See United States v. Navistar Int'l Corp.*, 240 F. Supp. 3d 789, 799 (N.D. Ill. 2017) (distinguishing *Flambeau* and noting that the fair notice concerns in that case do not apply where the statute or regulation at issue "could be ascertained from the text" of the statute or regulation).

In other words, Plaintiff does not challenge the lack of clarity or notice provided by the applicable statute and regulations as is required for a fair notice claim. *See id.*; *see also Flambeau Min. Co.*, 727 F.3d at 708 ("In determining whether a party received fair notice, courts frequently look to the regulations and other agency guidance. If, by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with ascertainable certainty, the standards with which the agency expects parties to conform, then the agency has fairly notified a petitioner[.]" (quotation omitted)). Instead, Plaintiff alleges and argues that Defendants are not acting pursuant to an emergency and therefore it lacks notice of Defendants' justification of the seal order. (R 54, Am. Compl. ¶¶ 38-57; R. 72, Resp. at 8-11.) This goes to the merits of Plaintiff's claim that Defendants violated state law and is not enough to allege a deprivation of due process. *See Tenny*, 659 F.3d at 583 (concluding that a procedural due process claim was not sufficiently alleged and

observing that "this case is really about a substantive violation of Illinois law, not about the procedures required before the plaintiffs can be deprived of a property interest").

Plaintiff also cites to *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155-56 (2012), but, like *Flambeau*, that case dealt with regulations that were unclear and did not give fair warning of the conduct that the regulations prohibited or required. So too did the other cases that Plaintiff cites. (R. 72, Resp. at 9[2] (citing *Gen. Elec. Co. v. U.S. Envtl. Prot. Agency*, 53 F.3d 1324, 1329-31 (D.C. Cir. 1995), *as corrected* (June 19, 1995); *United States v. Am. Nat. Can Co.*, 126 F. Supp. 2d 521, 530 (N.D. Ill. 2000)).) The Court, therefore, is unpersuaded by Plaintiff's argument that this is a case of "regulation by ambush." (R. 72, Resp. at 9.) Unlike *Flambeau* and the other cases Plaintiff relies on, Plaintiff does not allege that the language of Section 34(b) or any other statute or regulation affecting the Willowbrook facility fails to clearly convey what is required. (*See id.*) Instead, Plaintiff alleges that it lacked fair notice of Plaintiff's *justification* for invoking a statutory provision and that Defendant improperly invoked that provision, which are not the relevant considerations in *Flambeau* and the other fair notice cases that Plaintiff cites. *See, e.g.*, *Flambeau Min. Co.*, 727 F.3d at 708. Accordingly, Plaintiff fails to state a pre-deprivation procedural due process claim.

Turning to Plaintiff's post-deprivation procedural due process claim, to survive a motion to dismiss, Plaintiff must allege that there are inadequate procedures to challenge the seal order after it was issued. *Leavell*, 600 F.3d at 805-06; *see also Waldon v. Wilkins*, 400 F. App'x 75, 79-80 (7th Cir. 2010) ("For a party alleging such a procedural due process claim based on

[2] Plaintiff also relies on *United States v. Cinergy Corp.*, 623 F.3d 455, 458 (7th Cir. 2010), which stands for the proposition that the federal Clean Air Act does not authorize the imposition of sanctions for conduct that complies with a state's regulations promulgated under the Clean Air Act. That case, however, was brought by the federal government and concerned whether there had been a violation of the Clean Air Act, *Cinergy Corp.*, 623 F.3d at 456, not whether there had been a violation of due process, which is the precise question before the Court.

'random and unauthorized' conduct, the plaintiff must either avail himself of state post-deprivation remedies or demonstrate that the available remedies are inadequate." (quotations omitted)). Section 34(d) of the Act provides that the seal order can be challenged by an administrative hearing or by way of a lawsuit seeking "immediate injunctive relief." 415 ILL. COMP. STAT. 5/34(d); *see also, e.g.*, *Landfill, Inc. v. Pollution Control Bd.*, 387 N.E.2d 258, 260 (Ill. 1978) (ruling that a party may challenge an Illinois agency's action in state court if the action "is challenged as unauthorized"); *Tarkowski v. Ill. Envtl. Prot. Agency*, PCB 09-62, 2009 WL 1511352, at *2 (Ill. Pollution Control Bd. May 21, 2009) (hearing a request to lift a seal order issued pursuant to Section 34 of the Act). State courts supply the process due for random and unauthorized misconduct by state employees. *James v. Madigan*, 373 F. App'x 619, 621 (7th Cir. 2010). The ability to challenge the seal order in state court alone is enough to satisfy due process, and therefore Plaintiff fails to plausibly allege that it was deprived of an adequate post-deprivation hearing or process to challenge the seal order. *See Tucker v. Williams*, 682 F.3d 654, 661 (7th Cir. 2012) (concluding that there were adequate post-deprivation procedures available to the plaintiff where he could have brought a claim in state court); *Tenny*, 659 F.3d at 583 (noting that there was a viable post-deprivation remedy where "Illinois courts can and will entertain [the plaintiff's] claims and may grant injunctive and declaratory relief"); *see also Johnson v. Wallich*, 578 F. App'x 601, 602 (7th Cir. 2014) (affirming dismissal of due process claim because the plaintiff was afforded, by way of state statutes, procedures that could "address random, unauthorized deprivations of property by state officers and officials").

Plaintiff alleges that its options in state court are not ideal, but to allege an inadequate post-deprivation remedy, Plaintiff must plausibly allege that the post-deprivation remedies available in state court are "meaningless" or "nonexistent." *Easter House v. Felder*, 910 F.2d

1387, 1406 (7th Cir. 1990); *see also Simpson*, 860 F.3d at 1010 ("Though a state remedy need not match in every respect the relief otherwise available under § 1983, such a remedy must still offer meaningful redress for the particular injury suffered by the plaintiff."). Plaintiff does not plausibly allege that the procedures to challenge a seal order under Section 34(d) are meaningless or nonexistent; rather, Plaintiff alleges that the procedures are not as prompt and effective as those afforded under the federal Clean Air Act. (R. 54, Am. Compl. ¶¶ 54-57.) Though Plaintiff would prefer the procedures promulgated under federal law, due process does not require a process that is "afforded at the time and in the manner of one's own choosing." *Krison v. Nehls*, 767 F.2d 344, 349 (7th Cir. 1985). Nor is state law process inadequate simply because, as Plaintiff alleges, it fails to provide relief that is as "prompt" or "certain" as relief provided under federal law. *See Brunswick Corp. v. McNabola*, No. 16 CV 11414, 2017 WL 3008279, at *5 (N.D. Ill. July 14, 2017) (observing that "state-law relief is not deemed inadequate because it is far from certain and complete" and "litigants may lament that a particular forum may yield a more favorable result depending upon the nature of the claim and the particular position they support"(quotations omitted)). Accordingly, Plaintiff fails to state any claim for deprivation of its post-deprivation due process rights.

Given that Plaintiff fails to sufficiently allege a claim under Section 1983 or any other federal law, there are no pending federal claims that could provide grounds for subject-matter jurisdiction. *See* 28 U.S.C. § 1331. The Court also finds that supplemental jurisdiction would not

be appropriate over Plaintiff's Section 34(b) state-law claim.[3] *See* 28 U.S.C. § 1367; *Mains v. Citibank, N.A.*, 852 F.3d 669, 679 (7th Cir. 2017) ("[T]he federal claims were properly dismissed on the merits at a very early stage, and so the district court properly could relinquish its jurisdiction over the state claims."); *Miller v. Herman*, 600 F.3d 726, 738 (7th Cir. 2010) ("Normally, when all federal claims are dismissed before trial, the district court should relinquish jurisdiction over pendent state-law claims rather than resolving them on the merits." (quotation omitted)). Accordingly, both sovereign immunity and the lack of any federal question mandate dismissal of this action. Because the Court lacks jurisdiction, the Court need not reach Defendants' alternative argument that the Court should abstain from exercising jurisdiction pursuant to the principles in *Younger v. Harris*, 401 U.S. 37 (1971). The Court, therefore, dismisses the amended complaint without prejudice to Plaintiff seeking relief in state court.

[3] To the extent that Plaintiff asserts its Section 34(b) is a federal claim that provides a basis for federal question jurisdiction, the Court disagrees. Such jurisdiction cannot be premised on a Section 34(b) claim because, as addressed above and touched upon in Judge Lee's order, that claim arises out of state law. *See Int'l Union of Operating Eng'rs, Local 150, AFL-CIO v. Ward*, 563 F.3d 276, 281 (7th Cir. 2009) ("[W]hen the basis of the action is a federal statute, a federal cause of action must exist as well for a federal court to hear a given claim; the general grant of federal question jurisdiction contained in § 1331, without a federal cause of action, is not enough.").

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss (R. 63) is GRANTED as set forth herein. This case is DISMISSED without prejudice to Plaintiff litigating this dispute in state court.

ENTERED:

Chief Judge Rubén Castillo
United States District Court

Dated: May 3, 2019

IN THE CIRCUIT COURT OF THE EIGHTEENTH JUDICIAL CIRCUIT
DUPAGE COUNTY, ILLINOIS
CHANCERY DIVISION

PEOPLE OF THE STATE OF ILLINOIS, *ex rel.* LISA MADIGAN, Attorney General of the State of Illinois, and *ex rel.* ROBERT BERLIN, State's Attorney for DuPage County, Illinois,	)	
Plaintiff,	)	
v.	)	No. **2018CH001329**
STERIGENICS U.S., LLC, a Delaware limited liability company,	)	
Defendant.	)	

COMPLAINT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES

Plaintiff, PEOPLE OF THE STATE OF ILLINOIS, *ex rel.* LISA MADIGAN, Attorney General of the State of Illinois, on her own motion, and *ex rel.* ROBERT BERLIN, State's Attorney of DuPage County, Illinois, on his own motion, complain of the Defendant, STERIGENICS U.S., LLC, a Delaware limited liability company ("Sterigenics" or "Defendant"), as follows:

COUNT I
CAUSING, THREATENING OR ALLOWING AIR POLLUTION

1. This Count is brought on behalf of the People of the State of Illinois, *ex rel.* Lisa Madigan, Attorney General of the State of Illinois, on her own motion, and *ex rel.* Robert Berlin, State's Attorney of DuPage County, on his own motion, against the Defendant, pursuant to Sections 42(d) and (e) of the Illinois Environmental Protection Act ("Act"), 415 ILCS 5/42(d) and (e) (2016).

2. This Count is brought at the request of the Illinois Environmental Protection Agency ("Illinois EPA").

3. The Illinois EPA is an administrative agency of the State of Illinois, established by Section 4 of the Act, 415 ILCS 5/4 (2016), and is charged, *inter alia*, with the duty of enforcing the Act.

4. Since at least January 30, 2006, the Defendant has been and is a Delaware limited liability company duly authorized to transact business in the State of Illinois.

5. Since at least January 30, 2006 to present, on dates better known to the Defendant, the Defendant has operated an ethylene oxide gas ("EtO") commercial sterilization enterprise.

6. Sterigenics is comprised of two separate buildings located at 7775 South Quincy Street, Willowbrook, DuPage County, Illinois ("Building 1") and 830 Midway Street, Willowbrook, DuPage County, Illinois ("Building 2") (together, "Source").

7. In 1984, Griffith Micro Science, Inc. ("Griffith") began operating an EtO sterilization business at Building 1 of the Source.

8. In 1999, Ion Beam Applications acquired both Griffith and SteriGenics International, Inc. SteriGenics International, Inc. is the parent company of the Defendant. Between 1999 and 2006, SteriGenics International, Inc. was bought and sold multiple times.

9. On January 30, 2006, the Illinois EPA issued to the Defendant modified Clean Air Act Permit Program ("CAAPP") Permit No. 95120085 naming the Defendant as operator of the Source. Since 2006, the Defendant is the permitted operator of the Source.

10. Since 1984, at Building 1, and 1999, at Building 2, an EtO sterilization enterprise has been operating in Willowbrook.

11. From January 30, 2006 to present, on dates better known to the Defendant, the Defendant has operated at least fourteen commercial sterilizers at Building 1, and four commercial sterilizers at Building 2. Individual sterilizers are also known as "chambers".

12. Each commercial sterilizer is comprised of a steam-heated sterilization chamber, a recirculating vacuum pump chamber evacuation system, a backvent valve, and a fugitive emissions exhaust hood.

13. During the sterilization process, the Defendant places medical equipment and other products (together, "products") into individual chambers and EtO is introduced. During this process, the chambers are sealed. After a certain residence time, the Defendant evacuates EtO from the chambers. After the gas is pumped out of the chambers, air is introduced into the chambers. When air is introduced into the chambers, the chamber doors are opened and residual amounts of EtO are vented through the "backvent valves."

14. Upon completion of the sterilization cycle, EtO and other gases evacuated from the chambers in Building 1 are pumped to a Chemrox DEOXX packed tower chemical scrubber ("Acid Water Scrubber #1"), while the EtO from the chambers in Building 2 are routed to a two-stage Advanced Air Technologies Safe Cell emission-control system ("Willowbrook II Scrubber") and dry bed reactor.

15. After products are removed from the commercial sterilizers, they are placed in one of the Source's aeration rooms where EtO continues to volatilize, or off gas, from the sterilized products. There are three aeration rooms at Building 1 and two aeration rooms at Building 2. Emissions from the aeration rooms at Building 1 are captured and treated by a two-stage Advanced Air Technologies Safe Cell emission-control system ("Acid Water Scrubber #2") and dry bed reactor, and the emissions from the aeration rooms at Building 2 are captured and treated by the Willowbrook II Scrubber and dry bed reactor. The three scrubber systems and two dry bed reactors at the Source are collectively referred to as "the Scrubbers." The Scrubbers are the sole method used by the Defendant to control EtO emissions from the Source.

16. As part of its operations at the Source, the Defendant discharges and emits EtO to the atmosphere.

17. In 1990, EtO was listed as a "hazardous air pollutant" under Section 112 of the Clean Air Act, 42 U.S.C. § 7412(b)(1) (2016).

18. On June 8, 2015, the Illinois EPA issued renewal CAAPP Permit No. 95120085 to the Defendant ("Operating Permit"). The Operating Permit includes the Clean Air Act National Emission Standard for Hazardous Air Pollutants ("NESHAP") for EtO emissions from sterilization facilities. 40 C.F.R. Part 63, Subpart O. The NESHAP requires facilities to control EtO emissions from the vacuum pump chamber evacuation systems and aeration rooms by at least 99.0%. The NESHAP does not require that facilities control EtO emissions from the backvent valves. Therefore, the Operating Permit does not require the Defendant to control EtO emissions from the backvent valves at the Source.

19. The Operating Permit allows the Defendant to utilize up to 542.1 tons (1,084,200 pounds) of EtO per year in its operations at the Source.

20. Section 3.5.c of the Operating Permit provides as follows:

> **Annual Emissions Reporting**
>
> Pursuant to 35 IAC Part 254, the Source shall submit an Annual Emission Report to the [Illinois EPA], due by May 1 of the year following the calendar year in which the emissions took place. All records and calculations upon which the verified and reported data are based must be retained by the source.

21. Between 1984 and 1992, the Source emitted EtO.[1] Beginning in 1993 and continuing through 2005, the owner and or operator of the Source reported in its Annual Emission Reports releasing the following amounts of EtO to the atmosphere:

[1] Illinois EPA's Part 254 Rules (Annual Emissions Report) were first adopted on May 14, 1993. Hence, calendar year 1993 is the first Annual Emissions Report available for the Source.

Year	EtO Released (lbs.)
1993	10,780
1994	9,600
1995	21,320
1996	21,720
1997	30,800
1998	35,400
1999	15,940
2000	10,380
2001	6,146
2002	5,750
2003	5,200
2004	6,200
2005	5,800

22. According to the Defendant's Annual Emission Reports as filed by the Defendant with the Illinois EPA, the Defendant reported releasing the following amounts of EtO to the atmosphere during the years 2006 to 2017:

Year	EtO Released (lbs.)
2006	4,760
2007	7,340
2008	7,080

2009	5,600
2010	6,440
2011	6,980
2012	6,980
2013	5,960
2014	5,080
2015	4,600
2016	4,200
2017	4,600

23. On June 26, 2018, Illinois EPA issued the Defendant permit no. 18060020 to duct the emissions of EtO from the backvent valves of the sterilization chambers to the existing Scrubbers ("Construction Permit"). Illinois EPA received this construction permit application on June 11, 2018.

24. On information and belief, on or about July 27, 2018, the Defendant completed the modifications to its air pollution control equipment by ducting the emissions from the backvent valves at Building 1 to Acid Water Scrubber #2 and the dry bed reactor and the emissions from the backvent valves at Building 2 to Willowbrook II Scrubber and the dry bed reactor.

25. Prior to modifying its air pollution control equipment to control the emission of EtO from the backvent valves of the sterilization chambers, the Defendant allowed the uncontrolled emission of EtO from the backvent valves. As a result, since at least 2006, on a date better known to the Defendant, until on or about July 27, 2018, the Defendant had allowed the emission to the environment of 100% of the EtO that was released through the backvent valves.

26. The Operating Permit requires that the Defendant meet a control efficiency of 99.0% of emissions from the vacuum pump chamber evacuation system and aeration rooms. Once the backvent valves were ducted to the Scrubbers, those emissions also became and are subject to the 99.0% control efficiency.

27. The Operating Permit allows the Defendant to emit approximately 18.2 tons (36,400 pounds) of EtO per year.

28. EtO is highly reactive, readily absorbed, and easily distributed in the human body. EtO is mutagenic and causes chromosome damage in many species, including humans.

29. From 1985 to 2016, the United States Environmental Protection Agency. ("U.S. EPA") categorized EtO as "probably carcinogenic to humans".

30. In December 2016, U.S. EPA's Integrated Risk Information System ("IRIS") program released an "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide" ("2016 IRIS Evaluation"). In the 2016 IRIS Evaluation, U.S. EPA changed EtO's weight of evidence descriptor from "probably carcinogenic to humans" to "carcinogenic to humans" while increasing EtO's lifetime inhalation cancer unit risk estimate about 50-fold. The 2016 IRIS Evaluation is incorporated by reference herein.[2]

31. In the 2016 IRIS Evaluation, U.S. EPA noted that an increased incidence and mortality of breast and lymphohematopoietic system cancers have been observed in workers in EtO sterilizing facilities.

32. In the 2016 IRIS Evaluation, U.S. EPA determined that there is sufficient evidence to establish a causal relationship between EtO exposure and breast cancer in women.

[2] *Available at* http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=529970.

33. As a mutagenic carcinogen, EtO causes cancer by damaging DNA in cells which is then duplicated when the cells divide. Repeated exposure over time to EtO increases the cancer risk compared to a one-time exposure. This increase occurs because DNA damage may take place with each and every exposure that is passed on to more cells, increasing the number of mutated cells, which eventually leads to cancer in some people.

34. The Source is in a densely populated residential, industrial and commercial area, with 19,271 people living within 1 mile of the Source boundary. The Source is located in an industrial park that is surrounded by, and in close proximity to, residential neighborhoods, schools, daycare facilities, businesses, and parks, including but not limited to, the following:

i. Homes (less than 0.25 miles)

ii. Schools: Gower Middle (0.42 miles), St. Mark Christian Montessori (0.70 miles), Hinsdale South High School (0.76 miles), Gower West (0.79 miles), Kingswood Academy (0.87 miles), KinderCare (1.0 mile), Our Lady of Peace School (1.22 miles), Concord Elementary (1.62 miles), Ready Set Grow (1.76 miles), Burr Ridge Middle School (1.86 miles)

iii. Parks and Government Buildings: Willowbrook Police Department and Mayor's Office (0.07 miles), Willowbrook Community Park (0.45 miles), Indian Prairie Library (0.97 miles), Harvester Park (1.0 mile), Whittaker Park (1.03 miles), Burr Ridge Police Department (1.19 miles)

iv. Businesses: Dance Duo Studio (0.1 miles), Dell Rhea's Chicken Basket (0.16 miles), Denny's (0.18 miles), Target (0.19 miles), La Quinta Inn (0.29 miles), Red Roof PLUS+ (0.3 miles), Diamond Edge Training (0.3 miles), BIG Gymnastics (0.68 miles), Darien Sportsplex (1.0 mile)

35. According to U.S. EPA's website,[3] for a single year of exposure to EtO, the cancer risk is greater for children than for adults. This elevated risk to children exists because EtO can damage DNA, and children have more years ahead of them to develop the other cancer risk factors that result in the formation of malignant cells. Additionally, compared to adults, children receive

[3] *Available at* https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/frequent-questions-ethylene-oxide (accessed on October 18, 2018).

larger doses per body weight because they have greater lung surface area and increased lung volume per body weight, and breathe in more air per body weight.

36. According to 2010 U.S. Census Data, 3,494 children 5 years and younger lived within 3 miles of the Source in 2010, including 250 that lived within 1 mile.

37. According to the 2014 National Air Toxics Assessment ("NATA") released by U.S. EPA in August 2018, seven census tracts near the Source are among 109 nationwide that have cancer risk scores greater than 100 in 1 million, or 1 in 10 thousand, meaning that in those census tracts hazardous air pollution may cause more than one additional incidence of cancer per 10 thousand people. There are a total of 73,057 census tracts in the United States.

38. Between May 16, 2018 and May 17, 2018, the U.S. EPA collected 39 ambient air samples at 26 discrete locations near the Source ("May 2018 sampling event"). All of these samples were collected in proximity to the various public places listed in paragraph 34.

39. U.S. EPA modeled short and long-term ambient EtO concentrations to evaluate the impact of emissions from the Source using, among other data, the National Emissions Inventory ("NEI") data from 2014. The NEI data includes the actual pounds of EtO emitted by the Source, as reported by Illinois EPA, which is substantially lower than the amount of EtO that the Defendant is allowed to emit under the Operating Permit. As alleged in paragraph 22, the Defendant reported emitting 5,080 pounds of EtO in 2014, while as alleged in paragraph 27, the Operating Permit allows the emission of 18.2 tons, or 36,400 pounds, of EtO.

40. In June 2018, U.S. EPA provided the analytical data from the May 2018 sampling event and the modeled ambient EtO concentrations to the United States Department of Health & Human Services Agency for Toxic Substances and Disease Registry ("ATSDR"). At the same time, U.S. EPA: "requested that ATSDR review air measurements of EtO and modeling results of

EtO emissions from Sterigenics and specifically answer the question: If modeled and measured ethylene oxide concentrations represent long term conditions, would they pose a public health problem for people living and working in Willowbrook?"

41. On July 26, 2018, the ATSDR provided to U.S. EPA its answer to the above question. The letter provides:

> It is ATSDR's conclusion that the data U.S. EPA provided suggests that residents and workers are exposed to elevated airborne EtO concentrations from facility emissions. It is difficult to assess long-term public health implications from facility emissions because there has been no historical air monitoring in the community. ATSDR assumed that these data represent long term exposures for area residents and workers. Specifically, ATSDR concludes the following:
>
> 1) If measured and modeled data represent typical EtO ambient concentrations in ambient air, *an elevated cancer risk exists* for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated risks *present a public health hazard to these populations.*
>
> 2) Measured and modeled ethylene oxide concentrations in ambient air indicate that non-cancer health effects are unlikely for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility.

The July 26, 2018 ATSDR letter is attached hereto and incorporated by reference herein.

42. The ATSDR used the maximum recorded EtO sample taken near a residence close to the Source to conclude that the lifetime risk for the area surrounding the Source is an additional 64 incidences of cancer per 10,000 people, or 64 times what U.S. EPA considers to be an acceptable risk.

43. On August 21, 2018, the July 26, 2018 letter from ATSDR to U.S. EPA was released as a "Letter Health Consultation."

44. ATSDR's conclusion that an elevated cancer risk exists for residents and off-site workers in the Willowbrook community and that these elevated risks present a "public health hazard" is based on EtO emissions that are substantially lower than 18.2 tons (36,400 pounds).

Thus, the Operating Permit allows the "public health hazard" as found by the ATSDR in its report to continue unabated.

45. As of October 23, 2018, 28,925 people had signed a petition entitled "Action Alert: Illinois, Say "No" to toxic air" on the website www.change.org. The petition expresses the public's overwhelming concerns regarding the impact of Defendant's EtO emissions on the surrounding community. The concerns include the following:

i. Detrimental health impacts to their children swimming at a pool located across the street from the Source.

ii. The general safety of families in the area.

iii. The mutagenic effects of EtO on children in the area.

iv. Fear that past and current incidents of cancer in the area were caused by the Source.

v. A desire to have residents' children and grandchildren breathing safe air.

vi. The number of individuals in the community with cancer.

vii. Past exposure to EtO from the Source.

viii. The location of the Source in such a densely populated area.

46. As of October 24, 2018, more than 80 people have contacted the Illinois Attorney General's Office to express their concerns regarding the Source's EtO emissions.

47. As of October 24, 2018, the Illinois EPA has been contacted more than 100 times by members of the public to express their concerns regarding the Source's EtO emissions.

48. For those people who have resided near the Source over a period of years, the public health concerns with EtO are exacerbated due to the increased risk caused by exposure over a lifetime (see paragraphs 21 and 22, which show the Source's EtO emissions from 1993 to 2017,

including from 1995 to 1999, when the Source emitted, on average, more than 25,000 pounds of EtO annually to the environment).

49. Article XI of the Illinois Constitution provides, in pertinent part, as follows:

> SECTION 1. PUBLIC POLICY - LEGISLATIVE RESPONSIBILITY
>
> The public policy of the State and the duty of each person is to provide and maintain a healthful environment for the benefit of this and future generations. The General Assembly shall provide by law for the implementation and enforcement of this public policy.
>
> SECTION 2. RIGHTS OF INDIVIDUALS
>
> Each person has the right to a healthful environment. . . .

50. In fulfillment of the Constitutional requirement to protect each person's right to a healthful environment, the General Assembly adopted the Act. Section 9(a) of the Act, 415 ILCS 5/9(a) (2016), provides as follows:

> No person shall:
>
> a) Cause or threaten or allow the discharge or emission of any contaminant into the environment in any State so as to cause or tend to cause air pollution in Illinois, either alone or in combination with contaminants from other sources, or so as to violate regulations or standards adopted by the Board under this Act.

51. Section 201.141 of the Illinois Pollution Control Board ("Board") Air Pollution Regulations, 35 Ill. Adm. Code 201.141, provides, in relevant part, as follows:

> Prohibition of Air Pollution
>
> No person shall cause or threaten or allow the discharge or emission of any contaminant into the environment in any State so as, either alone or in combination with contaminants from other sources, to cause or tend to cause air pollution in Illinois, or so as to violate the provisions of this Chapter . . . .

52. Section 3.315 of the Act, 415 ILCS 5/3.315 (2016), provides the following definition:

> "Person" is any individual, partnership, co-partnership, firm, company, limited liability company, corporation, association, joint stock company, trust, estate, political subdivision, state agency, or any other legal entity, or their legal representative, agent or assigns.

53. The Defendant, a limited liability company, is a "person" as that term is defined in Section 3.315 of the Act, 415 ILCS 5/3.315 (2016).

54. Section 3.115 of the Act, 415 ILCS 5/3.115 (2016), provides the following definition:

> "Air pollution" is the presence in the atmosphere of one or more contaminants in sufficient quantities and of such characteristics and duration as to be injurious to human, plant, or animal life, to health, or to property, or to unreasonably interfere with the enjoyment of life or property.

55. Section 3.165 of the Act, 415 ILCS 5/3.165 (2016), provides the following definition:

> "Contaminant" is any solid, liquid, or gaseous matter, any odor, or any form of energy, from whatever source.

56. Section 201.102 of the Board Air Pollution Regulations, 35 Ill. Adm. Code 201.102, provides the following definitions:

> "Air Contaminant": Any solid, liquid or gaseous matter, any odor or any form of energy that is capable of being released into the atmosphere from an emission source.

57. The EtO released from the Facility is a "contaminant" within the meaning of Section 3.165 of the Act, 415 ILCS 5/3.165 (2016), and an "air contaminant" within the meaning of Section 201.102 of the Board Air Pollution Regulations, 35 Ill. Adm. Code 201.102.

58. Beginning on or before January 30, 2006 and continuing to the present, Defendant has discharged or emitted from the Source into the surrounding area thousands of pounds of EtO, which, as alleged herein, has caused or threatened injury to persons near the Source and unreasonably interfered with their enjoyment of life or property.

59. The Defendant's allowable emissions of approximately 18.2 tons (36,400 pounds) per year of EtO, a known human carcinogen, into the atmosphere near residences and places of business (a) threaten to injure the health of people living, attending school, recreating, working, and shopping near the Source, (b) have caused fear in the community due to the threat to public health, and (c) interfere with the enjoyment and use of their homes and work places, and therefore constitutes "air pollution" as that term is defined in Section 3.115 of the Act, 415 ILCS 5/3.115 (2016).

60. The threat to human health is particularly heightened in children, who have an increased susceptibility from exposure to a known human carcinogen. The unreasonable interference with enjoyment of life and property is particularly heightened for parents of children who live near the Source who are legitimately concerned about the health and welfare of their children as it relates to exposure to EtO, a known human carcinogen.

61. By causing, threatening, or allowing the discharge or emission of EtO, a contaminant, into the environment so as to cause air pollution, Defendant violated Section 201.141 of the Board Air Pollution Regulations, 35 Ill. Adm. Code 201.141, and Section 9(a) of the Act, 415 ILCS 5/9(a) (2016).

62. Violations of the pertinent environmental statutes and regulations will continue unless and until this Court grants equitable relief in the form of preliminary and, after trial, permanent injunctive relief.

WHEREFORE, Plaintiff, PEOPLE OF THE STATE OF ILLINOIS, respectfully requests this Court to enter a preliminary and, after trial, permanent injunction in favor of Plaintiff and against Defendant, STERIGENICS U.S., LLC, a Delaware limited liability company, with respect to Count I:

1. Finding that the Defendant has violated Section 9(a) of the Act, 415 ILCS 5/9(a) (2016), and Section 201.141 of the Board Air Pollution Regulations, 35 Ill. Adm. Code 201.141;

2. Enjoining the Defendant from any future violations of Section 9(a) of the Act, 415 ILCS 5/9(a) (2016), and Section 201.141 of the Board Air Pollution Regulations, 35 Ill. Adm. Code 201.141;

3. Setting operational limits on the Source, including ordering the Defendant to cease operations if warranted, or setting EtO emission limits on the Source so as to ensure the protection of public health and the elimination of the threat of air pollution in the surrounding community;

4. Ordering the Defendant to immediately undertake the necessary action that will result in a final and permanent abatement of violations of Section 9(a) of the Act, 415 ILCS 5/9(a) (2016), and Section 201.141 of the Board Air Pollution Regulations, 35 Ill. Adm. Code 201.141, including but not limited to, taking all steps necessary to ensure the protection of public health and the elimination of the threat of air pollution in the surrounding community, and performing ambient air monitoring at and around the Source in accordance with an approved sampling plan as well as conducting an updated cancer risk analysis. The ambient air monitoring and risk assessment shall be performed by independent contractors approved by the State and pursuant to plans approved by the State.

5. Assessing a civil penalty against the Defendant of Fifty Thousand Dollars ($50,000.00) for each violation of the Act and pertinent regulations, and an additional civil penalty of Ten Thousand Dollars ($10,000.00) for each day of violation;

6. Ordering the Defendant to pay all costs including attorney, expert witness and consultant fees expended by the State in its pursuit of this action pursuant to 415 ILCS 5/42(f) (2016); and

7. Granting such other relief as this Court deems appropriate and just.

COUNT II
COMMON LAW PUBLIC NUISANCE

1. This count is brought on behalf of the PEOPLE OF THE STATE OF ILLINOIS, *ex rel.* LISA MADIGAN, Attorney General of the State of Illinois, on her own motion, and *ex rel.* ROBERT BERLIN, State's Attorney of DuPage County, Illinois, on his own motion. The Attorney General is the chief legal officer of the State of Illinois having the powers and duties prescribed by the law, ILL. CONST. Article V, Section 15 (1970). The DuPage County State's Attorney is an elected county officer having the powers and duties prescribed by the law, ILL. CONST. Article VI, Section 19 and Article VII, Section 4 (1970). This count is brought pursuant to the power of the Attorney General and State's Attorney to institute an action on behalf of the People of the State of Illinois to abate a public nuisance and to protect the health, safety and welfare of the People of the State of Illinois.

2-59. Plaintiff realleges and incorporates by reference herein paragraphs 4 through 61 of Count I as paragraphs 2 through 59 of this Count II.

60. The Defendant, by its actions, has caused and continues to cause an unreasonable and substantial prejudice to the public health and welfare and the environment, to wit, 1) beginning on or before January 30, 2006 and continuing to the present, the Defendant has discharged or emitted from the Source into the surrounding area tens of thousands of pounds of EtO; 2) The Defendant's allowable emissions of approximately 18.2 tons (36,400 pounds) per year of EtO, a known carcinogen, into the atmosphere near residences and places of business (a) threaten to injure the health of people living and working near the Source, (b) have caused fear in the community due to the threat to public health, and (c) interfere with the enjoyment and use of their homes and work places.

61. As a consequence of its actions as alleged herein, the Defendant has created and maintained a public nuisance at common law.

62. Plaintiff is without an adequate remedy at law. Plaintiff will be irreparably injured, and violations of the applicable and pertinent environmental statutes and regulations will continue unless and until this court grants equitable relief in the form of preliminary and, after trial, permanent injunctive relief.

WHEREFORE, Plaintiff, PEOPLE OF THE STATE OF ILLINOIS, respectfully requests this Court to enter a preliminary and, after trial, permanent injunction in favor of Plaintiff and against Defendant, STERIGENICS U.S., LLC, a Delaware limited liability company, with respect to Count II:

1. Finding that the Defendant has created and maintained a common law public nuisance at and around the Source;

2. Setting operational limits on the Source, including ordering the Defendant to cease operations if warranted, or setting EtO emission limits on the Source so as to ensure the protection of public health and the elimination of the threat of air pollution in the surrounding community, and abatement of the public nuisance;

3. Enjoining the Defendant from maintaining a common law public nuisance at and around the Source;

4. Ordering the Defendant to immediately undertake the necessary action that will result in a final and permanent abatement of the common law public nuisance.

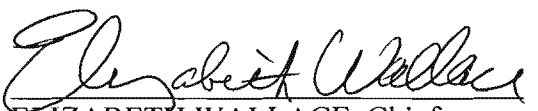
5. Ordering the Defendant to pay all costs including attorney, expert witness and consultant fees expended by the State in its pursuit of this action; and

6. Granting such other relief as this Court deems appropriate and just.

Respectfully submitted,

PEOPLE OF THE STATE OF ILLINOIS
ex rel. LISA MADIGAN, Attorney General
of the State of Illinois

MATTHEW J. DUNN, Chief
Environmental Enforcement/Asbestos
Litigation Division

BY: 
ELIZABETH WALLACE, Chief
Environmental Bureau
Assistant Attorney General

PEOPLE OF THE STATE OF ILLINOIS
ex rel. ROBERT B. BERLIN, State's
Attorney for DuPage County, Illinois

BY: 
LISA SMITH
Assistant State's Attorney

Of Counsel:

Daniel I. Rottenberg
Stephen J. Sylvester
Assistant Attorneys General
Environmental Bureau
69 West Washington Street, 18th Floor
Chicago, Illinois 60602
(312) 814-3816/2087
DRottenberg@atg.state.il.us
SSylvester@atg.state.il.us
Secondary: MCacaccio@atg.state.il.us

Appointment

From: Weinstock, Lewis [Weinstock.Lewis@epa.gov]
Sent: 2/25/2019 4:42:25 PM
To: Noah, Greg [Noah.Greg@epa.gov]; Chen, Xi [Chen.Xi@epa.gov]; Dyron.Hamlin@ghd.com; Benjamin.Chandler@ghd.com; Tim Halik [thalik@willowbrook.il.us]; RDemott@ramboll.com; Heidi Hayes [HeidiHayes@eurofinsUS.com]

Subject: Ethylene Oxide Laboratory/Methods Call Personal Email / Ex. 6 [code Personal Email / Ex. 6
Location: RTP-C400C-Max20/RTP-Bldg-C

Start: 2/27/2019 7:30:00 PM
End: 2/27/2019 8:30:00 PM
Show Time As: Tentative

Welcome to our first coordinating call among the groups measuring EtO in the ambient air around Willowbrook. The goal of this call (and others if needed) is to compare notes on the methods being used to report EtO along with any analytical challenges. We can also discuss any questions arising from our joint review of early February collocated sampling results and supporting data packages, assuming that there is sufficient time for a review prior to call. If not, a follow-up call will be scheduled.

Hope this time works for everyone.

Appointment

From: Weinstock, Lewis [Weinstock.Lewis@epa.gov]
Sent: 2/25/2019 4:45:05 PM
To: Noah, Greg [Noah.Greg@epa.gov]; Chen, Xi [Chen.Xi@epa.gov]; Dyron.Hamlin@ghd.com; Benjamin.Chandler@ghd.com; Tim Halik [thalik@willowbrook.il.us]; RDemott@ramboll.com; Heidi Hayes [HeidiHayes@eurofinsUS.com]

Subject: Ethylene Oxide Laboratory/Methods Call [202 991 0477] [code: Personal Email / Ex. 6
Location: RTP-C400C-Max20/RTP-Bldg-C

Start: 2/27/2019 7:00:00 PM
End: 2/27/2019 8:00:00 PM
Show Time As: Tentative

Welcome to our first coordinating call among the groups measuring EtO in the ambient air around Willowbrook. The goal of this call (and others if needed) is to compare notes on the methods being used to report EtO along with any analytical challenges. We can also discuss any questions arising from our joint review of early February collocated sampling results and supporting data packages, assuming that there is sufficient time for a review prior to call. If not, a follow-up call will be scheduled.

Hope this time works for everyone.

Message

From: Weinstock, Lewis [Weinstock.Lewis@epa.gov]
Sent: 2/25/2019 8:23:04 PM
To: RDemott@ramboll.com
CC: Heidi Hayes [HeidiHayes@eurofinsUS.com]; Chen, Xi [Chen.Xi@epa.gov]; Noah, Greg [Noah.Greg@epa.gov]
Subject: Willowbrook EtO ambient data for February sampling

Hi Bob:

How is your analysis coming along for the initial round of ambient sampling? We would be happy to share our QA data packages for early February if you are willing to do the same. Thanks!

Lewis Weinstock | Office of Air Quality Planning & Standards | U.S. Environmental Protection Agency | Research Triangle Park, NC 27711 | Phone: 919-541-3661|

Message

From: Weinstock, Lewis [Weinstock.Lewis@epa.gov]
Sent: 2/27/2019 1:49:52 PM
To: Noah, Greg [Noah.Greg@epa.gov]; Chen, Xi [Chen.Xi@epa.gov]; Dyron.Hamlin@ghd.com; Benjamin.Chandler@ghd.com; Tim Halik [thalik@willowbrook.il.us]; RDemott@ramboll.com; Heidi Hayes [HeidiHayes@eurofinsUS.com]; Compher, Michael [compher.michael@epa.gov]; Nwia, Jacqueline [nwia.jacqueline@epa.gov]
CC: Julie Swift [julie.swift@erg.com]; Koerber, Mike [Koerber.Mike@epa.gov]
Subject: Ethylene Oxide Laboratory/Methods Call [202 991 0477] [code: Personal Email / Ex. 6

Hi everybody:

We will have this call as scheduled today even though not all materials have yet been exchanged. This will be an opportunity to set expectations and compare notes about our respective efforts going forward. We will schedule a follow-up call after all data packages have been delivered and we all have had adequate time to review.

Thanks in advance for your participation

Lewis Weinstock | Office of Air Quality Planning & Standards | U.S. Environmental Protection Agency | Research Triangle Park, NC 27711 | Phone: 919-541-3661|

Message

From: Citizen Name / Ex. 6 Personal Privacy / Ex. 6
Sent: 11/12/2018 9:02:43 PM
To: Compher, Michael [compher.michael@epa.gov]; EtO [EtO@epa.gov]; mdjohnson@cdc.gov [mdjohnson@cdc.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]
Subject: Know the facts

Did you know...

EtO emissions as self-reported from Sterigenics

2016 - 4,205 pounds
2015 - 4,899 pounds
2014 - 5,241 pounds
2013 - 6,133 pounds
2012 - 7,099 pounds

But don't let those numbers fool you.

1998 - 32,200 pounds emitted
1997 - 27,020 pounds emitted

(They won't reveal emission data from 1989-1994)

But, we do know that

in 1988, they emitted 97,268 pounds of EtO into our air

in 1987, they emitted 169,466 pounds of EtO into our air

what about the years prior?

Will you stand up and demand that they shut down Sterigenics?

Citizen Name / Ex. 6

Sent from Mail for Windows 10

Message

From: Citizen Name / Ex. 6 Personal Privacy / Ex. 6
Sent: 11/28/2018 12:43:53 AM
To: bill.dart@illinois.gov; Brad.Frost@illinois.gov; mdjohnson@cdc.gov [mdjohnson@cdc.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]; state_scheduler@durbin.senate.gov; Alec.Messina@illinois.gov; Durkin@ILHouseGOP.org; chris@chrisnybo.org; Personal Email / Ex. 6 sen@ilhousegop.org; Senator John F. Curran Personal Privacy / Ex. 6; Senator Tammy Duckworth [correspondence@duckworth.senate.gov]; Personal Email / Ex. 6 sistance@StateRepCarolAmmons.com [Assistance@StateRepCarolAmmons.com]; RepDistrict3@gmail.com; butler@ilhousegop.org [butler@ilhousegop.org]; Personal Email / Ex. 6; sara@staterepsara.com [sara@staterepsara.com]; Personal Email / Ex. 6; staterepgabel@robyngabel.com Personal Email / Ex. 6 mike@repmikemarron.com [mike@repmikemarron.com]; mazzochi@ilhousegop.org [mazzochi@ilhousegop.org]; McDermed@ilhousegop.org [McDermed@ilhousegop.org]; Personal Email / Ex. 6 Personal Email / Ex. 6 killicorn@ilhousegop.org [skillicorn@ilhousegop.org]; arthurt@ilga.gov [arthurt@ilga.gov]; Personal Email / Ex. 6 Joel.creswell@mail.house.gov [Joel.creswell@mail.house.gov]; Compher, Michael [compher.michael@epa.gov]; EtO [EtO@epa.gov]; mdjohnson@cdc.gov [mdjohnson@cdc.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]
Subject: Individuals or Industry

Importance: High

Please do not let our community down by voting for the watered down bill proposed by Representative Carol Sente. That bill is a disgraceful sham. It will not help our community. It will allow Sterigenics to continue to release a carcinogenic chemical into our air. If you approve this bill, you are giving the industry the approval to continue poisoning our community. Every cancer diagnosed in this community will be on your hands. Every miscarriage. Every woman who fights breast cancer. All the individuals who have died from cancer in this area. All the children who will be exposed to further emissions. There is no safe amount of EtO to be in our air.

This hazardous chemical does not belong in populated areas. As long as Sterigenics is here, it is a clear and present danger to the residents.

Do not let this go any further. I am begging each and every one of you to please, PLEASE, represent the people, not the industry.

The EPA was not being honest with their recent report. **The ILEPA is being lead by Messina who was the Executive Director of the lobbyist group IERG. Do you not see what is happening here?**

Please, don't fall for the hype. My cancer is very real. The people who died from cancers linked to ethylene oxide will still be dead.

Do what you were elected to do – serve the people, not the profits.

History will remember what side of this issue you are on. It won't be kind if you stand against the residents in DuPage County or Lake County. The nation will soon be talking about EtO and your stance will be noted.

Day 98....

Citizen Name / Ex. 6

Sent from Mail for Windows 10

Message

From: Citizen Name / Ex. 6 Personal Privacy / Ex. 6
Sent: 11/20/2018 4:54:00 AM
To: Compher, Michael [compher.michael@epa.gov]; EtO [EtO@epa.gov]; mdjohnson@cdc.gov [mdjohnson@cdc.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]
Subject: still waiting

Today is Day 90. Little air cannisters have come and gone from our community and are on their way to labs. Results will be released in a few weeks. And, once again, the community is told to wait and that our local Villages, County, IEPA, State are doing everything to keep us safe. Sterigenics is running at full productivey 24/7/365 and, as a bonus, they are also running full-page ads in newspapers and online media downplaying any danger to the community.

Most people are shifting focus to the Thanksgiving Holiday just days away.

In 2009, after living 7 years in Willowbrook, just .7 miles from Sterigenics, I was diagnosed with stomach cancer. EtO has been linked to stomach cancer for decades. In January 2010, my stomach was completely removed. More surgeries followed. Now, I get nutrition via a j-tube and I am hooked up to it 17-hours a day. There are no Thanksgiving dinners in my future. I am not posting this for sympathy. I am posting this because we cannot idly wait for the IEPA or the test results. We cannot wait while Sterigenics attempts to dismiss the facts or diminish the risks that they pose. Don't get distracted.

These are the FACTS as I understand them. Fact: Sterigenics is emitting EtO molecules into our air 24/7/365. Fact: Sterigenics has emitted vast amounts of EtO into our air for the past 34 years. Fact: We are breathing in these molecules. Fact: EtO has been linked to a wide number of cancers, miscarriages, and other health issues. Fact: Thousands of pounds of EtO are being transported into our community each and every week. Fact: A single drum of EtO could cause a significant health disaster in our community.

How many molecules of EtO have we already inhaled? Are these molecules attached to a cell in our body? Are local mothers passing on EtO to their babies through breastmilk?

There is no safe amount of a carcinogenic. There are only acceptable risk limits that get lowered over time as our knowledge of the risks grows.

Day 90 – how many more molecules of EtO are you comfortable with our community inhaling?

Citizen Name / Ex. 6

Sent from Mail for Windows 10

Message

From: Citizen Name / Ex. 6 Personal Privacy / Ex. 6
Sent: 11/6/2018 10:24:32 PM
To: Compher, Michael [compher.michael@epa.gov]; EtO [EtO@epa.gov]; mdjohnson@cdc.gov [mdjohnson@cdc.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]
Subject: Waiting

Hold your breath

The average DuPage resident takes between 17,000 to 30,000 breaths per day.

In the 77 days since we learned about Sterigenics and the toxic EtO emissions, each DuPage resident has taken around 1.5 million breaths.

How many of our breaths brought EtO into our bodies?

How many of our cells are now stained with EtO?

How many breaths have been taken from our future?

How many of our loved ones are no longer breathing?

How many more days is it going to take?

We can't hold our breath waiting.

Take action today.

Sent from Mail for Windows 10

Message

From: Citizen Name / Ex. 6 Personal Privacy / Ex. 6
Sent: 12/2/2018 3:43:12 AM
To: Compher, Michael [compher.michael@epa.gov]; EtO [EtO@epa.gov]; mdjohnson@cdc.gov [mdjohnson@cdc.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]; Koerber, Mike [Koerber.Mike@epa.gov]; Davis, Alison [Davis.Alison@epa.gov]; Wilson, Holly [Wilson.Holly@epa.gov]
Subject: Understanding the numbers

Weekend update - Day 103: I have been trying to understand the impact of an 11-pound EtO emission event as was discussed on Thursday night. I have been pounding eleven pounds. Eleven pounds is a chunky cat. Eleven pounds might be a new size in clothing or just snugger clothing. What does this mean?

So, I asked someone who is very intelligent...I mean, really, really good with numbers. She has a PhD in Chemical Engineering. (Thank you Citizen Name / Ex. 6 for helping me understand.)

What I learned is comprehensible but INCOMPREHENSIBLE.

One molecule of EtO has the potential to mutate one human cell and trigger cancerous cell mutation. There are 6,200,000,000,000,000,000,000,000 molecules of EtO in one pound of EtO. A single 55-gallon drum of EtO contains 398.75 pounds of EtO.

That means that a single 55-gallon drum of EtO contains 2,472,225,000,000,000,000,000,000,000 EtO molecules.

It takes only one molecule of EtO to mutate one human cell into cancer.

Sterigenics stores upwards of 45 drums of EtO in the residential community of Willowbrook.

So, back to eleven pounds. That is a release of 68,200,000,000,000,000,000,000,000 EtO molecules. Molecules that will float in the air through our community and into the surrounding communities as far as the wind will take them for hundreds of days.

I have created spread sheets on Sterigenics Willowbrook's annual emissions for 34 years. I haven't done those calculations. I just haven't because there is no point to simply demonstrate my ability to use a calculator.

I hesitated to post this because writing it somehow makes it more real. But that fear was quickly replaced with anger and renewed determination. I am not going to ease up because I am afraid. I am going to raise my voice louder and rally more people. Now, you know the numbers. I honestly can't think of ONE single reason why there shouldn't be a total ban on the use of EtO.

Citizen Name / Ex. 6

Sent from Mail for Windows 10

Message

From: Citizen Name / Ex. 6 **Personal Privacy / Ex. 6**
Sent: 11/6/2018 1:58:54 AM
To: Compher, Michael [compher.michael@epa.gov]; EtO [EtO@epa.gov]; mdjohnson@cdc.gov [mdjohnson@cdc.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]
Subject: being abrasive

Shut down Sterigenics in Willowbrook.

Someone recently suggested that I might be a wee bit abrasive regarding this issue.

My response: We are trying to shut down a company that has been spewing toxic chemicals into the air we breathe for decades. We are not polishing heirloom silver.

If there is any issue where we need to be abrasive, it is this issue. We need to abrasively scrub this company out of our community.

After 76 days, I feel I haven't been abrasive enough.

When I see a school bus driving past that company, I worry that I haven't been abrasive enough.

When I look at my neighbors and hear their concerns...I definitely KNOW I have not been abrasive enough.

76 days....when will you become steel wool?

Citizen Name / Ex. 6

Sent from Mail for Windows 10

Appointment

From: Compher, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e258cb856e3d4ae6bacca7fa48ca827a-MCompher]
Sent: 5/2/2019 4:23:39 PM
To: Colledge, Michelle (ATSDR/DCHI/CB) [mna9@cdc.gov]

Subject: Accepted: Sterigenics Assessment Update for R5 Staff
Location: ATSDR office: R Personal Privacy /Conference Line/Code Ex. 6

Start: 5/9/2019 1:30:00 PM
End: 5/9/2019 3:00:00 PM
Show Time As: Busy

Message

From: Kristi Celico [K Personal Privacy / Ex. 6
Sent: 11/28/2018 10:45:38 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]; Wilson, Holly [Wilson.Holly@epa.gov]; doug@forumfg.com; Debra Duerr [tpc.llc@cox.net]; Cortelyou-Lee, Jan [Cortelyou-Lee.Jan@epa.gov]; Alec.Messina@illinois.gov; Donnell Margaret [Margaret.Donnell@hiscox.com]; thinshaw@indianheadpark-il.gov; Lauren Kaeseberg Personal Privacy / Ex. 6 ; Koerber, Mike [Koerber.Mike@epa.gov]; smolinaro@tristatefd.com; pbrenn@tristatefd.com; lawrencelink@tristatefd.com; Rimer, Kelly [Rimer.Kelly@epa.gov]
Subject: EPA Forum: Q and A Session at End

Hello:

This is an email about the final item on the forum agenda: the Public Q and A.

Obviously, it is not possible to have 1,000 folks ask questions at a meeting, so we have some ideas on how to organize this session. I have included on this email:

- All panel members (since you may be called back up to answer questions)
- The community volunteer asking questions: Lauren Kaeseberg of the Stop Sterigenics Group
- A couple EPA folks that might help.

Things are very busy and challenging for all right now, so I am going to propose a path forward and hopefully, we can have an email conversation to come to an agreement.

General Plan

The overall thought is to gather additional questions from the public and identify the ones that:

- Have not already been asked during other sessions; and
- That are of greatest concern to the community;

And have the questioner ask them on behalf of the community to all panel members. We only have ½ hour for this session, but EPA has agreed to answer most all the questions it receives in writing and post the answers on the web.

Where are the Questions Coming From?

Questions will come from the following sources:

- There is a table at the open house where people can write questions.
- People can write questions on index cards during the meeting.
- Some folks submitted questions to the EPA email address AFTER the Monday deadline. To the extent we have not been able to incorporate these quickly into sessions, we will try to address them here.

How are we going to identify the best questions to ask at the forum?

The ultimate decisions will be made by the community questioners. Currently, this is Lauren. Mayor Trilla was going to assist, but the Village counsel asked him not play this role. We will try to see if Mayor Hinshaw can assist. I have copied him here. Regardless, we need to staff the questioners. I suggest the following steps:

- EPA (Jan?) sort through the questions between now and the end of the open house and put them in 4 piles:
    - Very likely to have already been asked already during the sessions
    - Not appropriate for a public forum question
    - Great question of great concern to the public
    - Possible good question.
- At 6:00 p.m., Lauren, EPA, and I meet to sort through where we are at and come up with a list of most likely questions.
- During the meeting, the facilitators will collect additional questions from the crowd. We will try to identify any great questions and feed them into Lauren.

Who is going to answer the questions?

My thought is that we have all the panel members sitting in the front row and the questioners and the facilitators identify who should grab a mic and come answer the question. Also, panelists can put up their hand to grab our attention if you think you are the best responder or have something to add.

This is my proposal. I welcome thoughts and suggestions. If you have a concern about an approach, please suggest an improvement.

Thanks for your help and endurance on getting through this meeting!

Kristi Celico
Facilitator
--
Kristi Parker Celico
Public Policy Mediator/Facilitator

Personal Privacy / Ex. 6

Appointment

From: Compher, Michael [compher.michael@epa.gov]
Sent: 11/2/2018 4:08:07 PM
To: Coughlin, Justin [coughlin.justin@epa.gov]; Cummings, Carrie [cummings.carrie@epa.gov]; Delisio, Edward [delisio.edward@epa.gov]; Fuoco, Marta [fuoco.marta@epa.gov]; Hamilton, Scott [hamilton.scott@epa.gov]; McEvoy, Chad [mcevoy.chad@epa.gov]; Nwia, Jacqueline [nwia.jacqueline@epa.gov]; Qazzaz, Bilal [qazzaz.bilal@epa.gov]
CC: Siegel, Kathryn [siegel.kathryn@epa.gov]

Subject: Placeholder for Willowbrook EtO Fieldwork Training

Start: 11/7/2018 3:00:00 PM
End: 11/7/2018 8:00:00 PM
Show Time As: Tentative

Appointment

From: Compher, Michael [compher.michael@epa.gov]
Sent: 11/6/2018 9:28:03 PM
To: Coughlin, Justin [coughlin.justin@epa.gov]; Cummings, Carrie [cummings.carrie@epa.gov]; Delisio, Edward [delisio.edward@epa.gov]; Fuoco, Marta [fuoco.marta@epa.gov]; Hamilton, Scott [hamilton.scott@epa.gov]; McEvoy, Chad [mcevoy.chad@epa.gov]; Nwia, Jacqueline [nwia.jacqueline@epa.gov]; Qazzaz, Bilal [qazzaz.bilal@epa.gov]
CC: Siegel, Kathryn [siegel.kathryn@epa.gov]

Subject: Canceled: Placeholder for Willowbrook EtO Fieldwork Training

Start: 11/7/2018 3:00:00 PM
End: 11/7/2018 8:00:00 PM
Show Time As: Free

Importance: High

Appointment

From: Coughlin, Justin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D5E6E54DC1A4C62A892A97810249BEF-JCOUGHLIN]
Sent: 12/3/2018 9:51:35 PM
To: Nwia, Jacqueline [nwia.jacqueline@epa.gov]

Subject: Accepted: Willowbrook Monitoring: Midway Debriefing
Location: R5Metcalfe-ConfRm-R1815B/R5-Metcalfe---18th-Floor

Start: 1/15/2019 6:00:00 PM
End: 1/15/2019 7:00:00 PM
Show Time As: Busy

Message

From: Delisio, Edward [delisio.edward@epa.gov]
Sent: 3/7/2019 8:50:30 PM
To: Coughlin, Justin [coughlin.justin@epa.gov]
Subject: site locations
Attachments: epa site locations.xlsx

Here's Jackie's file…(it has site 9, that was never operational)

Edward Delisio
USEPA Region 5
Chicago, Illinois
ph.312-886-1303
fx. 312-692-2044
delisio.edward@epa.gov

Site Number	ERG Site Name	QAPP Site Name	Site Address/Nearest Cross Streets
1	WB Village Hall	Willowbrook Village Hall	825 Midway Dr., Willowbrook, IL
2	EPA WB Warehouse	EPA Willowbrook Warehouse	600 Joliet Rd, Willowbrook, IL
3	Gower MS	Gower Middle School	7941 S. Madison St., Burr Ridge, IL
4	West Neighborhood	West Neighborhood	7635 Eleanor Pl., Willowbrook, IL
5	Water Tower	Water Tower	700 Willowbrook Center Pkwy, Willowbrook, IL
6	Willow Pond Park	Willowbrook Pond/Kiwanis Pavilion Park	7760 Adams St., Willobrook, IL
7	Hinsdale South HS	Hinsdale South High School	7401 Clarendon Hills Rd, Darien, IL
8	Gower ES	Gower Elementary School	7650 Clarendon Hills Rd., Willowbrook, IL
9	Eisenhower JH	Eisenhower Junior High	1410 75th Street, Darien, IL

Latitude	Longitude
41.748589	-87.941090
41.747438	-87.938739
41.743462	-87.933294
41.748763	-87.94556
41.755363	-87.939163
41.763981	-87.939845
41.753685	-87.948497
41.748835	-87.956179
41.753003	-87.978947

Message

From: Coughlin, Justin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D5E6E54DC1A4C62A892A97810249BEF-JCOUGHLIN]
Sent: 12/14/2018 4:20:36 PM
To: Compher, Michael [compher.michael@epa.gov]; Nwia, Jacqueline [nwia.jacqueline@epa.gov]
Subject: Water testing

FYI - https://news.wttw.com/2018/12/13/regulators-test-water-70-homes-near-sterigenics-willowbrook

Justin Coughlin
Air Monitoring and Analysis Section
Air & Radiation Division | US EPA Region 5
312.886.0778 | Coughlin.justin@epa.gov

Appointment

From: Coughlin, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d5e6e54dc1a4c62a892a97810249bef-JCoughlin]
Sent: 12/3/2018 9:51:35 PM
To: Nwia, Jacqueline [nwia.jacqueline@epa.gov]

Subject: Accepted: Willowbrook Monitoring: Midway Debriefing
Location: R5Metcalfe-ConfRm-R1815B/R5-Metcalfe---18th-Floor

Start: 1/15/2019 6:00:00 PM
End: 1/15/2019 7:00:00 PM
Show Time As: Busy

Message

From: Louie, Brian [BLouie@lakecountyil.gov]
Sent: 2/5/2019 4:42:46 PM
To: Davis, Alison [Davis.Alison@epa.gov]
Subject: FW: Data for Lake County, Illinois EtO Webpage
Attachments: Ethylene Oxide Emissions Data.xlsx

Hi Alison,

About a month ago, I emailed you a request to add the information mentioned below and attached to this email to the USEPA's webpage: https://www.epa.gov/il/addressing-ethylene-oxide-emissions-lake-county-illinois. We believe that by including this data on the webpage, we can maintain transparency with our residents, as well as continuing to maintain a single source of information. I understand that you and your team were out of the office due to the shutdown when I submitted my original email, so I am hoping that we can revisit this request.

Thank you,

Brian Louie
Senior Marketing and Communications Specialist
Lake County Health Department and Community Health Center
O: (847) 377-8356 Personal Privacy / Ex. 6
E: BLouie@lakecountyil.gov | health.lakecountyil.gov/
Follow us: Facebook | Twitter | LinkedIn

From: Louie, Brian
Sent: Monday, January 7, 2019 11:41 AM
To: 'Davis, Alison' <Davis.Alison@epa.gov>
Subject: Data for Lake County, Illinois EtO Webpage

Hi Allison,

Upon learning about the ethylene oxide emissions concerns in Lake County, Illinois in November, the Lake County Health Department submitted a FOIA request to the Illinois EPA in order to compare and contrast EtO emissions at Sterigenics, Medline, and Vantage. A spreadsheet was created to summarize the information found in the request (see attached). Mark Pfister, Executive Director Health Department, is requesting that the USEPA posts this data on the following webpage: https://www.epa.gov/il/addressing-ethylene-oxide-emissions-lake-county-illinois. We believe that by including this data on the webpage, we can maintain transparency with our residents, as well as continuing to maintain a single source of information.

I understand that the EPA websites are not currently being regularly updated, however, please let me know when we can expect to see this information added to the webpage.

As a reminder, Hannah Goering started her maternity leave back in December, so I will be your contact at the Lake County Health Department until she returns at the end of February.

Please let me know if you have any questions.

Thank you,

Brian Louie
Senior Marketing and Communications Specialist

Lake County Health Department and Community Health Center
O: (847) 377-8356 | M Personal Privacy / Ex. 6
E: BLouie@lakecountyil.gov | health.lakecountyil.gov/
Follow us: Facebook | Twitter | LinkedIn

Message

From: Delisio, Edward [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9319E61692214D5897DE4181B1D61D67-EDELISIO]
Sent: 11/2/2018 3:59:20 PM
To: Coughlin, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d5e6e54dc1a4c62a892a97810249bef-JCoughlin]; Cummings, Carrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c9c7adf225b4d33903c884703ca6c52-Cummings, C]; Qazzaz, Bilal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=779fa066f1974031969ce3f09a410d78-BQazzaz]; Hamilton, Scott [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc13937a4dca4048a621ec1bb378d894-Smhamilt]; Delisio, Edward [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9319e61692214d5897de4181b1d61d67-EDelisio]; Fuoco, Marta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acb697586be74cf2ac37b0f4e221da97-MFuoco]; McEvoy, Chad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47e7e24a4df14138917bbee65d8e8a08-CMcEvoy]; Compher, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e258cb856e3d4ae6bacca7fa48ca827a-MCompher]
Subject: Delisio, Edward is inviting you to collaborate on Willowbrook 2018_2019 Monitoring

llinois/Shared%20Documents/Willowbrook%202018_2019%20Monitoring/Willowbrook%202018_2019%20Sample%20Ca

This link only works for the direct recipients of this message.

Willowbrook 2018_2019 Monitoring

Open

Microsoft OneDrive

Message

From: Padovani, Steven [padovani.steven@epa.gov]
Sent: 2/12/2019 8:37:12 PM
To: Divita, Sonny [divita.sonny@epa.gov]
Subject: EtO video

https://www.csb.gov/sterigenics-ethylene-oxide-explosion/

The video explaining what happened in 2004 at the another Sterigenics facility. It explains the sterilization process too.

S-

Message

From: Divita, Sonny [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=57A3FBFBED314A96BA025F728E30F458-SDIVITA]
Sent: 2/6/2019 3:04:49 PM
To: Padovani, Steven [padovani.steven@epa.gov]
Subject: FYI
Attachments: Willowbrook EtO Data Maps as of 1-31-19.pptx

Steve,

FYI on results so far.

Sonny Divita
U.S. Environmental Protection Agency
Region 5 | Superfund Division | Field Services
77 W. Jackson Blvd. (SFS-5J) | Chicago, IL 60604
Phone: 312-353-1247

From: Nwia, Jacqueline
Sent: Wednesday, February 6, 2019 8:26 AM
To: Delisio, Edward <delisio.edward@epa.gov>; Fuoco, Marta <fuoco.marta@epa.gov>; Hamilton, Scott <hamilton.scott@epa.gov>; Qazzaz, Bilal <qazzaz.bilal@epa.gov>; McEvoy, Chad <mcevoy.chad@epa.gov>; Cummings, Carrie <cummings.carrie@epa.gov>; Coughlin, Justin <coughlin.justin@epa.gov>; Divita, Sonny <divita.sonny@epa.gov>
Cc: Compher, Michael <compher.michael@epa.gov>
Subject: Willowbrook Results

A few updates:

- For those of you that are interested:
  - Willowbrook website: https://www.epa.gov/il/sterigenics-willowbrook-facility
  - Map with data through end of January and Windroses is in the attached PDF file (please don't distribute. OAQPS will load up onto the public website).
- Sterigenics and the Village of Willowbrook will be conducting their own air sampling in the next few weeks. Don't be surprised if you see additional tripods and canisters at some of our sites:
  - GHD is the Village of Willowbrook's contractor who will be collocating with our samples at Village Hall, Water Tower and the 2 Gower schools (elementary and middle)
  - Ramboll is Sterigenics' contractor who will be sampling at Village Hall and EPA Warehouse site.
  - Please note in the logbook and chain of custody forms interactions with either contractor and whether canisters are collocated at the sites.
  - If contractors need a minute or two to start canisters at same time as ours, please afford them that opportunity.
  - I am in the process of updating the contact forms with the contractor field personnel phone and email.
- NEW ADDITION TO CANISTER COLLECTION PROCEDURE: When ambient air temperature is 10 degrees F or lower, please follow these instructions to take a Final, Final (indoor) pressure for each canister:
  - ERG/OAQPS noticed large final pressure differences between our final field pressure and pressure taken at ERG prior to analysis. If this difference is greater than 3 inches of Hg, canister must be invalidated per the QAPP.
  - The large pressure difference was identified for one event in January during THE coldest air temperature day (-3 to 2 degrees F). To assist in avoiding invalidations that are not due to leaking canisters, please take a final, final pressure once all canisters are returned to the Warehouse and canisters are afforded 10-15 minutes to warm up. Once canisters are warmed up, cap the regulator with the silver cap AS

TIGHT AS YOU COULD GET IT, open the canister valve, take the final pressure. Record the Final, Final pressure on the chain of custody by separating it from the final field pressure with a slash and the following **(indoor final).** Make note of the process in the logbook and chain of custody.

I think those are all the updates I have for now. Please let me know if you have any questions.

Jackie

Jacqueline Nwia
Environmental Scientist
Air Monitoring and Analysis Section
Air Toxics and Assessment Branch
Air and Radiation Division
U.S. Environmental Protection Agency, Region 5
77 West Jackson Blvd. (AR-18)
Chicago, IL 60604
ph. (312) 886-6081
nwia.jacqueline@epa.gov

Message

From: Divita, Sonny [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=57A3FBFBED314A96BA025F728E30F458-SDIVITA]
Sent: 11/27/2018 7:27:26 PM
To: Padovani, Steven [padovani.steven@epa.gov]
Subject: Fw: Air Monitoring using Canisters

Steve,

Looks like Jackie is going to be deploying canisters tomorrow and collecting on Thursday. I haven't had a chance to get involved yet. I was planning on staying in Chicago to take care of the credit cards, but if you think Mike could handle that, I would be interested in coming back tomorrow and Thursday to learn about the air sampling.

Let me know,

Sonny Divita
U.S. Environmental Protection Agency
Region 5 - Superfund
Field Services Section
77 W. Jackson Blvd.
Chicago, IL 60604
Mail Stop SFS-5J
Phone: 312-353-1247

From: Nwia, Jacqueline
Sent: Tuesday, November 27, 2018 11:44 AM
To: Divita, Sonny
Subject: Air Monitoring using Canisters

Hi Sonny,

We met briefly at Willowbrook. I'm leading the ethylene oxide canister monitoring effort near Sterigenics. Steve thought you may be interested in getting trained and participating deploying and collecting canisters. We are monitoring for the next 3 months so there are opportunities but we'll need to train you. Alternatively, if you're just interested in learning how to use canisters, etc., there is also opportunity for that as well. We will be out tomorrow, Wednesday, to deploy for the next sampling event and Thursday to collect. Let me know if you're available and interested. We should be at the willowbrook facility between 8:15 – 8:30 am.

Jackie

Jacqueline Nwia
Environmental Scientist
Air Monitoring and Analysis Section
Air Toxics and Assessment Branch

Air and Radiation Division
U.S. Environmental Protection Agency, Region 5
77 West Jackson Blvd. (AR-18)
Chicago, IL 60604
ph. (312) 886-6081
nwia.jacqueline@epa.gov

Message

From: Durno, Mark [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=664882445D1B4824800B1E52ED01307E-MDURNO]
Sent: 6/19/2018 4:36:52 PM
To: Borries, Samuel [borries.samuel@epa.gov]; Ribordy, Michael [ribordy.mike@epa.gov]; Brown, Jaime [brown.jaime@epa.gov]
CC: El-Zein, Jason [el-zein.jason@epa.gov]
Subject: FW: Scheduled time for COOP Exercise at Willowbrook

Since we have staff working at Willowbrook, you all should be aware of this…

Mark Durno
Homeland Security Advisor
Emergency Response Branch
U.S. Environmental Protection Agency
25063 Center Ridge Road
Westlake, OH 44145
440-250-1743

From: Durno, Mark
Sent: Tuesday, June 19, 2018 12:32 PM
To: Hersh, Stuart <hersh.stuart@epa.gov>; Cohen, Eric <cohen.eric@epa.gov>; Colquitt, Cynthia <colquitt.cynthia@epa.gov>; Klassman, Debra <klassman.debra@epa.gov>; Lupton, Jane <lupton.jane@epa.gov>; Kyte, Larry <kyte.larry@epa.gov>
Cc: Arrazola, Ignacio <arrazola.ignacio@epa.gov>; Frey, Bert <frey.bertram@epa.gov>; Nelson, Leverett <nelson.leverett@epa.gov>; Glover, John <Glover.John@epa.gov>; Padovani, Steven <padovani.steven@epa.gov>
Subject: RE: Scheduled time for COOP Exercise at Willowbrook

Thanks for the heads-up Stu,

Also copying Steve Padovani, who is our manager responsible for the SF warehouse.

Mark

Mark Durno
Homeland Security Advisor
Emergency Response Branch
U.S. Environmental Protection Agency
25063 Center Ridge Road
Westlake, OH 44145
440-250-1743

From: Hersh, Stuart
Sent: Tuesday, June 19, 2018 12:25 PM
To: Cohen, Eric <cohen.eric@epa.gov>; Colquitt, Cynthia <colquitt.cynthia@epa.gov>; Klassman, Debra <klassman.debra@epa.gov>; Lupton, Jane <lupton.jane@epa.gov>; Kyte, Larry <kyte.larry@epa.gov>
Cc: Arrazola, Ignacio <arrazola.ignacio@epa.gov>; Frey, Bert <frey.bertram@epa.gov>; Nelson, Leverett <nelson.leverett@epa.gov>; Glover, John <Glover.John@epa.gov>; Durno, Mark <durno.mark@epa.gov>
Subject: RE: Scheduled time for COOP Exercise at Willowbrook

Thank you Eric.

Deliberative Process / Ex. 5

I am requesting that you Deb and Jane identify a few dates that would work for the three of you to conduct this training. We can then discuss these options with Bert, Rett, Larry and Ignacio to identify the best option(s).

By copy of this message, I am also informing the Regional Health and Safety Officer and the Region's Homeland Security manager, as this information impacts their duties and may impact the standing staff at the SF warehouse located at the back of the COOP location. I am available to assist on this matter in any way that I can.

Thank you again,

Stuart P Hersh
Associate Regional Counsel
Region 5
US EPA
312-886-6235

From: Cohen, Eric
Sent: Tuesday, June 19, 2018 11:15 AM
To: Colquitt, Cynthia <colquitt.cynthia@epa.gov>; Klassman, Debra <klassman.debra@epa.gov>; Lupton, Jane <lupton.jane@epa.gov>; Kyte, Larry <kyte.larry@epa.gov>
Cc: Hersh, Stuart <hersh.stuart@epa.gov>
Subject: RE: Scheduled time for COOP Exercise at Willowbrook

Cynthia:
One of the reasons I can't participate in the Coop exercise is because of a meeting with the RA tomorrow about ethylene oxide emissions from the Sterigenics facility in Willowbrook. Ethylene oxide is a carcinogen and the Sterigenics facility is emitting it. The modelling we have done shows concentrations at the Sterigenics property fenceline in amounts that create unacceptable risk. The Sterigenics plant is next to our Willowbrook facility. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Sterigenics.
eric

From: Colquitt, Cynthia
Sent: Tuesday, June 19, 2018 9:25 AM
To: Klassman, Debra <klassman.debra@epa.gov>; Cohen, Eric <cohen.eric@epa.gov>; Lupton, Jane <lupton.jane@epa.gov>
Cc: Hersh, Stuart <hersh.stuart@epa.gov>; Ortiz, Mary <ortiz.mary@epa.gov>; Weatherspoon, Darlene <weatherspoon.darlene@epa.gov>
Subject: RE: Scheduled time for COOP Exercise at Willowbrook

Good Morning everyone, from what I can see in my messages, we are still on for tomorrow. I have a vehicle reserved to take us there. Please plan to meet me in the lobby at 10:30am. Thanks.

From: Klassman, Debra
Sent: Tuesday, June 19, 2018 9:20 AM
To: Colquitt, Cynthia <colquitt.cynthia@epa.gov>; Cohen, Eric <cohen.eric@epa.gov>; Lupton, Jane <lupton.jane@epa.gov>
Cc: Hersh, Stuart <hersh.stuart@epa.gov>; Ortiz, Mary <ortiz.mary@epa.gov>; Weatherspoon, Darlene <weatherspoon.darlene@epa.gov>
Subject: RE: Scheduled time for COOP Exercise at Willowbrook

Morning. Are we still leaving the office at 10:30 am tomorrow?

From: Colquitt, Cynthia
Sent: Wednesday, June 06, 2018 1:39 PM
To: Cohen, Eric <cohen.eric@epa.gov>; Klassman, Debra <klassman.debra@epa.gov>; Lupton, Jane <lupton.jane@epa.gov>
Cc: Hersh, Stuart <hersh.stuart@epa.gov>; Ortiz, Mary <ortiz.mary@epa.gov>; Weatherspoon, Darlene <weatherspoon.darlene@epa.gov>
Subject: RE: Scheduled time for COOP Exercise at Willowbrook

Thanks everyone for getting back to me. I will go ahead and confirm June 20th at 10:30am – 1pm returning to the office. I will also reserve a GSA vehicle for this COOP exercise. Please look for a calendar invite. Thanks.

From: Colquitt, Cynthia
Sent: Wednesday, June 6, 2018 12:16 PM
To: Cohen, Eric <cohen.eric@epa.gov>; Klassman, Debra <klassman.debra@epa.gov>; Lupton, Jane <lupton.jane@epa.gov>
Cc: Hersh, Stuart <hersh.stuart@epa.gov>; Ortiz, Mary <ortiz.mary@epa.gov>; Weatherspoon, Darlene <weatherspoon.darlene@epa.gov>
Subject: Re: Scheduled time for COOP Exercise at Willowbrook

Hello everyone, after consulting with the front office, the date for this exercise is best on Friday, June 29th at 10:00 – 2:00pm. Please let me know if you can work with us on this date. Thanks so much.

From: Colquitt, Cynthia
Sent: Wednesday, June 6, 2018 10:14 AM
To: Cohen, Eric <cohen.eric@epa.gov>; Klassman, Debra <klassman.debra@epa.gov>; Lupton, Jane <lupton.jane@epa.gov>
Cc: Hersh, Stuart <hersh.stuart@epa.gov>; Ortiz, Mary <ortiz.mary@epa.gov>; Weatherspoon, Darlene <weatherspoon.darlene@epa.gov>
Subject: FW: DRAFT - Scheduled time for COOP Exercise at Willowbrook

Hi all,

As ORC managers, you may be required to be the lone ORC representative at the COOP site during a COOP event. The Region is preparing a COOP exercise that may occur as early as late June. Stuart and I are inviting you to a COOP site tour to include training on the COOP and DEVOP. We are proposing that this training occur the morning of June 18th , 19th or 20th. If one of these dates/times do not work for you, please propose alternatives. We recommend that you bring your EPA computer, cell phone and Go Kit backpacks (if EPA provided these to you) to this training (and each COOP event).

The COOP site is located on Joliet Road in Willowbrook, Illinois, about a 40+ minute drive from downtown. You have the option of driving on your own from your home (or elsewhere) to the COOP site or joining us as we drive from EPA's Chicago office (we will schedule a GSA vehicle). We propose leaving the EPA office at about 10 am, arriving at the Willowbrook COOP site at about 11 am, with the tour and training completed at about 12 pm. If interested and your schedules permit, there is a restaurant that Bert recommends for its chicken a couple of blocks away. We should be able to return to ORC's offices between 1 pm and 2 pm, depending on whether we have lunch together.

Please identify your date/time preferences for this training and we will provide you with a confirmation.

Thank you,

Cynthia Colquitt
U.S. EPA
Management and Program Analyst

(312) 886-6238 Work
colquitt.cynthia@epa.gov

77 West Jackson Blvd.
Chicago, IL 60604

Message

From: Holst, Linda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=97E4A65ADDD9494FA193C98DD5D12B55-LHOLST]
Sent: 12/14/2018 2:35:22 AM
To: Stepp, Cathy [stepp.cathy@epa.gov]; Thiede, Kurt [thiede.kurt@epa.gov]; Payne, James [payne.james@epa.gov]; Nam, Ed [nam.ed@epa.gov]; Kelley, Jeff [kelley.jeff@epa.gov]
CC: Baltazar, Debbie [baltazar.debbie@epa.gov]; Poy, Thomas [poy.thomas@epa.gov]
Subject: Willowbrook water sampling
Attachments: Willowbrook Well Sampling News Release - Draft.docx; 2018_12_11 DCN242 QAPP010 for Ethylene Glycol and Ethylene Oxide Sampling.docx

Cathy, Kurt and Jim - Based on Tom Poy's email exchanges with Rick Cobb at IEPA, samples were collected today and sent to the labs today. The turnaround is 7-8 days. Results should be available end of Dec/early Jan.

Linda

Acting Director | Water Division | EPA Region 5
(312) 886-6758 | holst.linda@epa.gov

Quality Assurance Project Plan:

Ethylene Glycol and Ethylene Oxide Sampling of Private Drinking Water Wells Near Sterigenics

Prepared by:

Rick Cobb, P.G.
Deputy Division Manager
Division of Public Water Supplies
Bureau of Water

and

Michelle Rousey
Quality Assurance Officer
Bureau of Water
(217) 785-3944

Illinois Environmental Protection Agency (Illinois EPA)
1021 North Grand Avenue East
P.O. Box 19276
Springfield, IL 62794-9276

December 2018

SECTION A. PROJECT MANAGEMENT

A1 Approval Sheet

_____ _____

Rick Cobb, P.G.
Illinois EPA Bureau of Water, Deputy Division Manager,
Headquarters, Division of Public Water Supplies

Date

_____ _____

Michelle Rousey
Illinois EPA Bureau of Water, Quality Assurance Officer

Date

A2 Table of Contents

[TOC \o "1-3" \h \z \u]

Acronyms and Abbreviations

ATSDR	Agency for Toxic Substance and Disease Registry
BOW	Bureau of Water
CAR	Corrective Action Report
CFR	Code of Federal Regulations
DCHD	DuPage County Health Department
DPWS	Division of Pubic Water Supplies
DQOs	Data Quality Objectives
EPA	Environmental Protection Agency
EtO	Ethylene Oxide
FID	Flame Ionization Detector
GC	Gas Chromatography
GIS	Geographical Information System
GWS	Groundwater Section
HAPs	Hazardous Air Pollutants
HTTAC	Human Threshold Toxicant Advisory Concentration
IDPH	Illinois Department of Public Health
LCS	Laboratory Control Sample
MACT	Maximum Achievable Control Technology
MDL	Method Detection Limit
mg/L	Milligrams per Liter
mL	Milliliter
MMOs	Minimum Measurement Objectives
MS	Mass Spectrometry

MS	Matrix Spike
MSD	Matrix Spike Duplicate
NELAC	National Environmental Laboratory Accreditation Conference
NESHAP	National Emission Standards for Hazardous Air Pollutants
NIST	National Institute for Standards and Technology
QA	Quality Assurance
QAO	Quality Assurance Officer
QAPP	Quality Assurance Project Plan
QC	Quality Control
RL	Reporting Limit
RPD	Relative Percent Difference
SOP	Standard Operating Procedure
TNI	The NELAC Institute
USEPA	United States Environmental Protection Agency
VOA	Volatile Organic Analysis

A3 Distribution List

A copy of this Quality Assurance Project Plan (QAPP) will be distributed in electronic format via e-mail to each person signing the approval sheet and also to the individuals listed in Section A4 Project/Task Organization. Individuals participating in this study may request additional copies of the QAPP from personnel listed in Section A4.

An electronic copy of the QAPP will be posted on the Illinois EPA Intranet system via the Illinois EPA Portal: Illinois EPA Compass > SharePoint Site Directory > Bureau of Water > Bureau of Water Quality System > BOW Quality Assurance Project Plans.

The original approved QAPP containing the Approval Sheet with signatures and dates will be retained by the Illinois EPA Bureau of Water (BOW) Quality Assurance Officer (QAO).

This document has been prepared according to the United States Environmental Protection Agency (USEPA) publication *EPA Requirements for Quality Assurance Project Plans (QA/R-5)* (May 2001).

A4 Project/Task Organization

An organizational chart illustrating the ethylene glycol and ethylene oxide sampling study group hierarchy is presented in Figure 1. (Table 1 contains contact information for the study group.)

The following individuals are responsible for project management:

Study Director/Manager/Coordinator – Rick Cobb, P.G., Deputy Division Manager, Illinois EPA, Headquarters, Division of Public Water Supplies (DPWS), BOW.

Quality Assurance Officer – Michelle Rousey, Environmental Protection Specialist IV, QAO, Illinois EPA, Headquarters, Bureau Chief's Office, BOW.

Network Design Coordinator -- Joe Konczyk, Environmental Protection Geologist III, Illinois EPA, Headquarters, Groundwater Section (GWS), DPWS, BOW.

Sample Collectors –

Greg White, P.G., Environmental Protection Specialist III, Illinois EPA, Rockford Regional Office, GWS, DWPS, BOW.

Ryan Bennett, Environmental Protection Geologist III, Illinois EPA, Headquarters, GWS, DPWS, BOW.

Joe Konczyk, Environmental Protection Geologist III, Illinois EPA, Headquarters, GWS, DPWS, BOW.

Alan Fuhrmann, Environmental Protection Geologist III, Illinois EPA, Headquarters, GWS, DPWS, BOW.

Kari Beckum, Environmental Protection Geologist I, Illinois EPA, Headquarters, GWS, DPWS, BOW.

Public Health Coordinator – Aaron Martin, Toxicology and Indoor Air Quality Program Manager, Illinois Department of Public Health (IDPH), Division of Environmental Health.

Seewald Laboratories, Inc:

Raymond Martrano, Laboratory Director
Christopher M. Fuller, Quality Director
Samantha Merrill, Project Manager

TestAmerica Pensacola Laboratory:

Brian Spann, Laboratory Director
Lance Larson, Quality Assurance Manager
Carol Webb, Project Manager

The Study Director/Manager/Coordinator is responsible for oversight of the entire project including design, funding, implementation, data receipt and review, reporting, and preparation of the QAPP.

The Illinois EPA BOW QAO, in consultation with the Study Director/Manager/Coordinator, is responsible for oversight of quality control (QC) for the project and will assist in preparing the QAPP. The QAO will review and approve this QAPP as meeting the QAPP requirements in USEPA's publication QA/R-5. The QAO will conduct audits if deemed necessary.

The Network Design Coordinator, in consultation with the Study Director/Manager/Coordinator is responsible for the design of the network and selection of wells.

The Sample Collectors are responsible for coordinating the execution of field activities.

The Public Health Coordinator is responsible for reviewing and providing the laboratory results to the private well owners with an interpretive letter explaining the sample results.

Seewald Laboratories, Inc. is responsible for the preparation, analysis, data generation, and data reporting of the environmental samples for ethylene glycol.

The TestAmerica Pensacola laboratory is responsible for the preparation, analysis, data generation, and data reporting of the environmental samples for ethylene oxide.

A5 Problem Definition and Background

The Illinois EPA upholds those standards established by the state Environmental Protection Act, the federal Clean Air Act and the corresponding regulations. Illinois EPA is the regulatory Agency that inspects, permits and ensures that facilities comply with the applicable rules and regulations.

Sterigenics US LLC operates a hospital implement sterilization facility at 7775 Quincy Street and 830 Midway in Willowbrook. The facility uses ethylene oxide to sterilize hospital equipment/implements. Implements to be sterilized are placed in a chamber and ethylene oxide is introduced to the chamber. After a certain residence time, the chamber is evacuated of ethylene oxide. After the gas is pumped out of the chamber, air is introduced into the chamber. When air is introduced into the chamber, residual amounts of ethylene oxide are vented through a "back vent."

Sterigenics is currently controlling the back vents at the facility with a scrubber. The company recently had stack testing of back vent emissions done, as required by Illinois EPA permit #18060020, to verify the performance of the scrubber. The stack testing was performed in accordance with USEPA stack test guidance and the stack test plan was approved by Illinois EPA. Both Illinois EPA and USEPA observed the stack testing. Final results from the stack test showed no measurable Ethylene Oxide (EtO) emissions after the scrubber. A full stack test report will be submitted to the Illinois EPA in the next few weeks.

USEPA identifies certain chemicals as hazardous air pollutants (HAPs). One such chemical is Ethylene Oxide (EtO). USEPA regulates facilities that have emissions of HAPs by setting National Emission Standards for Hazardous Air Pollutants (NESHAP). The intent of a NESHAP is to protect public health by requiring existing and new major sources to control emissions to the level achievable by the maximum achievable control technology (MACT).

Periodically, USEPA reevaluates HAPs by reviewing the most recent scientific studies to ensure up-to-date risk categorizations and to determine if updates need to be made to a NESHAP. USEPA recently updated the risk profile for EtO, significantly reducing the acceptable exposure level. As a result of the updated risk profile, USEPA has begun to assess sources that use EtO for purposes of updating the NESHAP. Hospital equipment sterilization facilities are a user of EtO. The NESHAP for sterilization facilities has not yet been changed.

As part of its review, USEPA identified Sterigenics in Willowbrook as a user of EtO and conducted modeling of the emissions from the facility. USEPA then performed ambient air sampling around the facility in May of 2018 and forwarded that information to the Agency for Toxic Substance and Disease Registry (ATSDR), the federal public health agency, for a public health assessment to help USEPA evaluated the need for regulatory changes that may be needed to the sterilization facility NESHAP. ATSDR produced a Health Consultation Report and summarized its findings in an e-mail to the Village of Willowbrook,

"The emissions of ethylene oxide from the Sterigenics International, Inc. facility in Willowbrook, IL **are not an immediate threat to public health and are not considered to be an emergency situation**. ATSDR recommended to U.S. EPA that actions be taken to reduce emissions of ethylene oxide from this facility to protect the public from long-term exposures that could harm their health.

The conclusion in the ATSDR Letter Health Consultation report,

"If measured and modeled data represent typical EtO ambient concentrations in ambient air, an elevated cancer risk exists for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These evaluated risks present a public health hazard to these populations"

is to inform and support the regulatory decisions being made by the state and EPA to reduce emissions from that facility to protect public health.

ATSDR based this conclusion on estimated cancer risks that are calculated using conservative assumptions about a lifetime exposure to the highest levels of ethylene oxide that were measured in Willowbrook commercial and residential areas near the facility. The highest measured levels of ethylene oxide in those areas were about 1,000 times lower than levels associated with cancer risks in scientific studies of workers with industrial exposure to EtO."

In June 2018, Sterigenics requested a construction permit from the Illinois EPA to control emissions of EtO from the back vents with a scrubber. Illinois EPA issued a construction permit for the scrubber and it has been in operation since the end of July. Scrubbers are a known technology for controlling emissions and typically have a greater than 90% efficiency. The scrubber has reduced emissions from the facility. Sterigenics is required to stack test to verify the level of control from the stack.

As noted above, USEPA previously conducted modeling and sampling. It is important that any additional sampling and modelling conform to the same criteria that was previously used so that the results may be directly correlated to the previous sampling event. The Illinois EPA has requested that USEPA perform additional modeling and monitoring and reassess the risk assessment now that emissions from the facility have been significantly reduced.

A6 Project/Task Description

In response to questions and concerns of residents and local officials in Willowbrook and the surrounding area, the Illinois EPA and DuPage County Health Department announced on November 8, 2018 in a Private Well Sampling News Release (Appendix A) their coordinated effort to identify private wells and obtain access from homeowners to sample private wells near the Sterigenics facility.

The Illinois EPA, in a letter (Appendix B) dated November 15, 2018 to residents with private water wells in the areas in or near the communities of Willowbrook, Darien and Burr Ridge, Illinois, requested residents complete a short survey regarding their well water and provide permission to obtain a groundwater sample to be tested at no cost to the resident.

The surveys and Geographical Information System (GIS) information were used to analyze the wells relative to the proximity of the Sterigenics site to determine sampling locations.

Laboratories were selected and procured based on qualifications and accreditation to The NELAC (National Environmental Laboratory Accreditation Conference) Institute Standards.

The NELAC Institute's Mission Statement:

> The NELAC Institute (TNI) is a 501(c)(3) non-profit organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent

process that is responsive to the needs of the community. The organization is managed by a Board of Directors and is governed by organizational [HYPERLINK "http://nelac-institute.org/docs/TNI-Bylaws-Rev7-04-17-17-Approved.pdf"].

TNI's vision is a true national accreditation program, whereby all entities involved in the generation of environmental measurement data within the United States are accredited to one uniform, rigorous, and robust program that has been implemented consistently nationwide and focuses on the technical competence of the entity pursuing accreditation. TNI believes such a program will improve the quality and reliability of environmental data used by federal and state agencies. (https://nelac-institute.org/content/aboutus.php)

Seewald Laboratories, Inc in Williamsport, PA was chosen to analyze water samples for ethylene glycol. Seewald Laboratories is one of only two laboratories with NELAC accreditation for ethylene glycol analysis in drinking water. The laboratory is accredited by the Commonwealth of Pennsylvania Department of Environmental Protection, Bureau of Laboratories, Laboratory Accreditation Program (Appendix C).

The TestAmerica Pensacola Laboratory in Pensacola, FL was chosen to analyze water samples for ethylene oxide. TestAmerica Pensacola has NELAC accreditation for ethylene oxide analysis in non-potable water. (There are no laboratories with NELAC accreditation for ethylene oxide analysis in drinking water.) The laboratory is accredited by the State of Illinois EPA, Environmental Laboratory Accreditation Program (Appendix D) as the Secondary Accrediting Authority. The Primary Accrediting Authority for TestAmerica Pensacola is the Florida Department of Health, Bureau of Laboratories.

There are no Illinois laboratories with NELAC accreditation for ethylene glycol analysis in drinking water or ethylene oxide analysis in non-potable water.

Up to 200 private drinking water wells will be sampled for ethylene glycol and ethylene oxide. Sampling will be conducted by Illinois EPA staff from the Groundwater Section, Division of Public Water Supplies, Bureau of Water. A map of residential sampling in the area of Sterigenics in Willowbrook, IL is presented in Figure 2.

A7 Quality Objectives and Criteria

A summary of the minimum measurement criteria and data quality objectives (DQOs) for samples analyzed by the Seewald and TestAmerica laboratories are presented in Table 2.

A7.1 Precision

Precision is a measure of agreement among repeated measurements of the same property under identical, or substantially similar, conditions; calculated as either the range or as the standard deviation. Precision may also be

expressed as a percentage of the mean of the measurements, such as relative range or relative standard deviation (coefficient of variation).

Precision will be measured in the laboratory during the analysis of matrix spike (MS) and matrix spike duplicate (MSD) samples. The frequency of the analysis will be one MS/MSD per batch of 20 environmental samples.

The analyses of the duplicate samples are considered acceptable if the calculated relative percent difference (RPD) of the measurements is within the acceptance limits listed in Table 2.

The results of the duplicate analyses are used to calculate the RPD for evaluating precision using the following formula:

$$RPD = [(A - B) / (A + B)/2] * 100$$

where

A = Original sample concentration

B = Duplicate sample concentration

A7.2 Bias

Bias is the systematic or persistent distortion of a measurement process that causes errors in one direction.

A7.3 Accuracy

Accuracy is a measure of the overall agreement of a measurement to a known value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations.

Accuracy will be measured during the analysis of environmental water by using Laboratory Control Samples (LCSs). In the laboratory, samples of deionized water will be fortified (or spiked) with the analytes of interest. These LCS samples will be analyzed with each batch of water extracts. The analyses of the LCS samples are considered acceptable if the calculation concentrations for all analytes of interest are within the acceptance limits listed in Table 2.

The results of the spiked samples are used to calculate the percent recovery for evaluating accuracy using the following formula:

Percent Recovery = [(S - U) / T] * 100

Where

S = Spiked sample concentration

U = Unspiked sample concentration

T = True spike concentration

A7.4 Representativeness

Representativeness is the measure of the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.

Representativeness of data will be ensured using established field and laboratory procedures and their consistent application. To aid in the evaluation of the representativeness of the sample data, trip and laboratory blank samples will be evaluated for the presence of contaminants.

Trip blank samples will be used to check for contamination of ethylene glycol and ethylene oxide samples during handling, storage, and shipment from the field to the laboratory. Each sample collector will place two trip blank samples in the individual cooler(s) used to ship the samples to the respective laboratories.

A7.5 Comparability

Comparability is a measure of the confidence with which one data set or method can be compared to another.

Comparability will be maximized by using standard analytical methods and standardized, documented sampling techniques. Documentation will include all sampling locations, conditions, and field sampling methods. All results will be reported in standard units or, for field parameters, as defined in the method. All laboratory calibrations will be performed using standards traceable to the National Institute for Standards and Technology (NIST) or another certified reference standard source.

A7.6 Completeness

Completeness is a measure of the amount of valid data needed to be obtained from a measurement system.

The percent completeness is calculated by dividing the number of valid sample results by the total number of samples planned, and multiplying the result by 100 percent. Completeness will be reported as the percentage of all measurements judged valid. The following equation will be used to determine completeness:

Percent Completeness = (V/T) * 100

where

V = Valid number of sample results

T = Total number of samples planned

For this project, the QA objective for degree of completeness for both field and laboratory data is 90 percent. If completeness is less than the target of 90 percent the Study Director/Manager/Coordinator, and QAO will evaluate the data to determine whether there are enough data to complete the study or if additional data collection is necessary.

A7.7 Sensitivity

Sensitivity is the capability of a method or instrument to discriminate between measurement responses representing different levels of the variable of interest.

Although there are many intended and potential uses of the data, minimum measurement criteria will be established at the lowest analyte concentration required for planned uses of the measurement data. Minimum measurement criteria are typically groundwater standards or health advisory standards; however, due to a lack of these standards, the minimum measurement criteria for ethylene glycol will be the Human Threshold Toxicant Advisory Concentration (HTTAC) (Appendix E). The HTTAC was calculated using the Groundwater Quality Standards, Subpart F methodologies and assumptions. The minimum measurement objectives (MMOs) will be established at the lowest analyte concentrations (reporting limits) achievable by the Seewald and TestAmerica laboratories. The monitored parameters and minimum measurement criteria and objectives are shown in Table 2.

The MMO for any analyte will be achieved when the analytical procedure selected for sample analysis can be shown to have a method detection limit (MDL) at or below the MMO. Table 2 compares the MMOs against the reporting limits achieved by the Seewald and TestAmerica laboratories. All analytes meet the MMO.

Analyte MDLs shall be determined by the USEPA method given in the Code of Federal Regulations (CFR), Volume 40, Part 136, Appendix B. The MDL is defined as "the minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results." Since the MDL procedure is based upon precision obtained for a standard greater than the MDL, it also is a measure of method sensitivity at concentrations near the MDL.

A8 Special Training/Certifications

Prior to sample collection, all sample collectors shall be trained in the proper groundwater sample collection procedures (Appendix F) and any special sampling instructions provided by the laboratories.

A9 Documentation and Records

Sample collection records of all field activities shall be retained in the permanent record. The Sample Collector is responsible for coordinating the execution of those field activities. Sample collection records shall document proper sampling protocol performed in the field.

The Study Director/Manager/Coordinator shall retain all laboratory analytical results and all correspondence with the Seewald and TestAmerica laboratories. Chain of Custody sheets (Appendices G and H) submitted for the laboratory shall also be retained along with analytical results.

All records will be archived with the Agency's Division of Records Management, following their protocols, and maintained in a secure location at the Agency Headquarters in Springfield.

The QAO shall be made aware of any problems encountered during any phase of the project.

SECTION B. DATA GENERATION AND ACQUISITION

B1 Sampling Process Design (Experimental Design)

The Illinois EPA Network Design Coordinator used data obtained from the DuPage County Health Department (and collated by the DuPage County GIS) to create a map (Figure 2) using ESRI, ArcGIS. The map shows the area of concern and the potential sampling sites near the Sterigenics site in Willowbrook, IL. The Illinois EPA Groundwater Section will use the map to determine sampling locations and prioritize sample collection activities.

B2 Sampling Methods

Ethylene glycol and ethylene oxide samples will be collected following proper groundwater sample collection procedures (Appendix F) and any special sampling instructions provided by the laboratories. Sample containers, volumes, parameters, methods, preservatives, and holding times are summarized in Table 3.

The samples will be analyzed for ethylene glycol by Seewald Laboratories, Inc.

The samples will be analyzed for ethylene oxide by the TestAmerica Pensacola laboratory.

Refer to Section B5.1 Field Quality Control for individuals responsible for corrective action.

B3 Sample Handling and Custody

All samples are to be shipped to Seewald and TestAmerica laboratories within the prescribed holding times.

All samples are to be accompanied by completed Chain of Custody sheets (Appendices G and H).

The laboratories shall record sample temperature upon arrival at the laboratory using a thermometer calibrated against a NIST traceable certified thermometer. Samples that require thermal preservation are refrigerated after sample acceptance at the laboratory.

When received by the laboratory, the samples are logged into the laboratory logbook and/or laboratory database. Maximum holding times before analysis, as stated in applicable methods and Standard Operating Procedures (SOPs), are followed.

Sample disposal shall follow the procedures stated in each laboratory's Quality Assurance Manual.

Refer to Section B5.2 Laboratory Quality Control for individuals responsible for corrective action.

B4 Analytical Methods

Ethylene glycol samples will be analyzed by the Seewald Laboratories, Inc. following the approved laboratory SOP (Appendix I) and USEPA Method 8015D (Appendix J) which are listed in Table 4.

Ethylene oxide samples will be analyzed by the TestAmerica Pensacola laboratory following the approved laboratory SOP (Appendix K) and USEPA Method 8260B (Appendix L) which are listed in Table 5.

The ethylene glycol and ethylene oxide turnaround time from sample receipt to reporting of the sample results is 7 days.

B5 Quality Control

B5.1 Field Quality Control

All field operations personnel are responsible for ensuring proper sampling methods, sample preservation, and sample custody of the delivered samples to the designated laboratory are followed.

An investigation and corrective action report (CAR) prepared by the responsible supervising field personnel in the event of a QC issue will be submitted to the Study Manager/Coordinator. The Study Manager/Coordinator will then forward this report to the QAO.

The accuracy and precision of all data measurements must be quantifiable. Analytical procedures used for data analysis must be performed in accordance with approved methods. Data measurements should be recorded in a controlled environment in which a QC program is maintained.

B5.2 Laboratory Quality Control

The Seewald and TestAmerica laboratories (and any subcontracted laboratory) are each responsible for implementing their laboratory QA Manual (Appendices M and N) which is an internal QA plan for laboratory procedures. The laboratories are responsible for the accuracy and reliability of analytical methods and final data reports according to their QA Manuals.

An investigation and CAR will be submitted to the Study Director/Manager/Coordinator and the QAO as QC issues arise. The Seewald and TestAmerica laboratories are responsible for providing data qualifiers and/or case narratives to inform the Study Director/Manager/Coordinator and the QAO of any analytical exceptions that fall outside of routine method protocols. Each laboratory's QA Manual will contain the procedures for QC and for calculating QC statistics.

B6 Instrument/Equipment Testing, Inspection, and Maintenance

All laboratory equipment shall be routinely maintained according to the manufacturer's manuals. Any equipment used for field data measurements shall be tested and inspected prior to sampling events.

An adequate supply of spare parts shall be maintained by the laboratory and field operations personnel for equipment maintenance. Spare parts shall be routinely inventoried.

B7 Instrument/Equipment Calibration and Frequency

Laboratory instruments shall be calibrated according to the laboratory SOPs, methods, and QA Manual. The laboratory shall also keep adequate records of equipment calibration and use NIST traceable standards when possible.

The frequency of the instrument calibrations shall follow the laboratory SOPs, methods, and QA Manual.

B8 Inspection/Acceptance of Supplies and Consumables

Supplies and consumables used in the field shall be inspected by the field operations staff to guarantee their usability. Supplies and consumables used in laboratory procedures shall be inspected by the laboratory manager to confirm compliance with the laboratory SOPs and QA Manual.

B9 Non-direct Measurements

Non-direct measurements are not required for this study.

B10 Data Management

Logbooks, field measurement records, and other data gathered in the field (i.e., chain of custody sheets) shall be maintained in the permanent record. All records will be archived with the Agency's Division of Records Management, following their protocols, and maintained in a secure location at the Agency Headquarters in Springfield.

The Seewald and TestAmerica laboratories will convey all laboratory analytical data using their standard laboratory report format to the Study Manager/Coordinator. A .pdf of the report, along with a simple Excel Electronic Data Deliverable will be sent to Illinois EPA. All data communicated to the Illinois EPA shall be verified the Study Manager/Coordinator for reliability and usability.

SECTION C. ASSESSMENT AND OVERSIGHT

C1 Assessments and Response Actions

Evaluations will be documented by the Study Manager/Analysis Coordinator and submitted to the QAO. QC issues related to field activities will require an investigation and corrective action plan submitted to the Study Manager/Coordinator and QAO.

The Seewald and TestAmerica laboratories involved in data analysis shall each maintain an internal QA program described in their laboratory QA Manual (Appendices M and N). The laboratories shall maintain QC checks for procedures. When the possibility of QC problems arise that may affect the usability of data, an investigation and CAR will be submitted by the Laboratory Manager to the Study Manager/Coordinator and reviewed by the QAO.

Also, the Study Manager/Coordinator shall make certain that the project data associated with any QC or other nonconformance issue is made available to data users with the appropriate data qualification. When data

previously released to data users may have been affected by a QC problem or other nonconformance issue, the Study Manager/Coordinator shall notify other data users of the problem.

C2 Reports to Management

The Study Manager/Coordinator will receive investigation and CARs in case of any QC issue and will forward these reports to the QAO. Reports shall be prepared by the QAO documenting the QC issue, the corrective action taken, and the outcome of the corrective action and how it impacts the data.

Any QA problems affecting the final reported values shall be reported to the Study Manager/Coordinator and any other data users.

SECTION D. DATA VALIDATION AND USABILITY

D1 Data Review, Verification, and Validation

The Study Manager/Coordinator and the Public Health Coordinator will review final analytical reports and address any issue related to data reliability as mentioned in pertinent investigation and correction action plans. Laboratory results with accompanying data qualifiers will be listed as such in any reports or data submitted to the Study Manager/Coordinator. It will be the responsibility of the Study Manager/Coordinator to determine the usability of any qualified data.

D2 Verification and Validation Methods

Sample collection and field measurement records shall be verified by Sample Collectors and sent to the Study Manager/Coordinator. Laboratory data shall be verified by the Laboratory Manager. Field and laboratory records will be archived with the Agency's Division of Records Management, following their protocols, and maintained in a secure location at the Agency Headquarters in Springfield.

In the case of data verification resulting in a change to data, the Study Manager/Coordinator shall document any corrections.

The Study Manager/Coordinator shall be informed if data accuracy, reliability, or usability has been reduced as the result of errors in stored data or corrupted data files. The Study Manager/Coordinator shall make any necessary corrections to the data and document the reasons the corrections were made.

D3 Reconciliation with User Requirements

The Study Manager/Coordinator shall review data and its usability and determine if it meets the requirements of the study objectives as stated in Section A5, Problem Definition and Background.

The execution of the study shall follow the procedures outlined in this QAPP. Personnel listed in Section A4, Project/Task Organization are responsible for implementation of the QC measures during each stage of the project.

The QAPP shall be reviewed by all persons listed on the approval page. The review shall determine issues to be addressed as the project progresses. Issues to be discussed may include:

1. The number and location of sampling stations.
2. The frequency of sampling.
3. Sampling procedures.
4. Parameters measured.
5. Data quality objectives and minimum measurement criteria.
6. Analytical procedures.
7. Project reporting.
8. Corrective actions taken.

The study shall be modified only as directed by the Study Manager/Coordinator. Changes in procedures shall not be made without the approval of the Study Manager/Coordinator. All changes shall be documented in a memorandum that will be distributed to those listed on the Approval Sheet.

The QAO shall update the QAPP after review and keep a separate record of changes.

FIGURES

Figure 1 – Study Organizational Chart

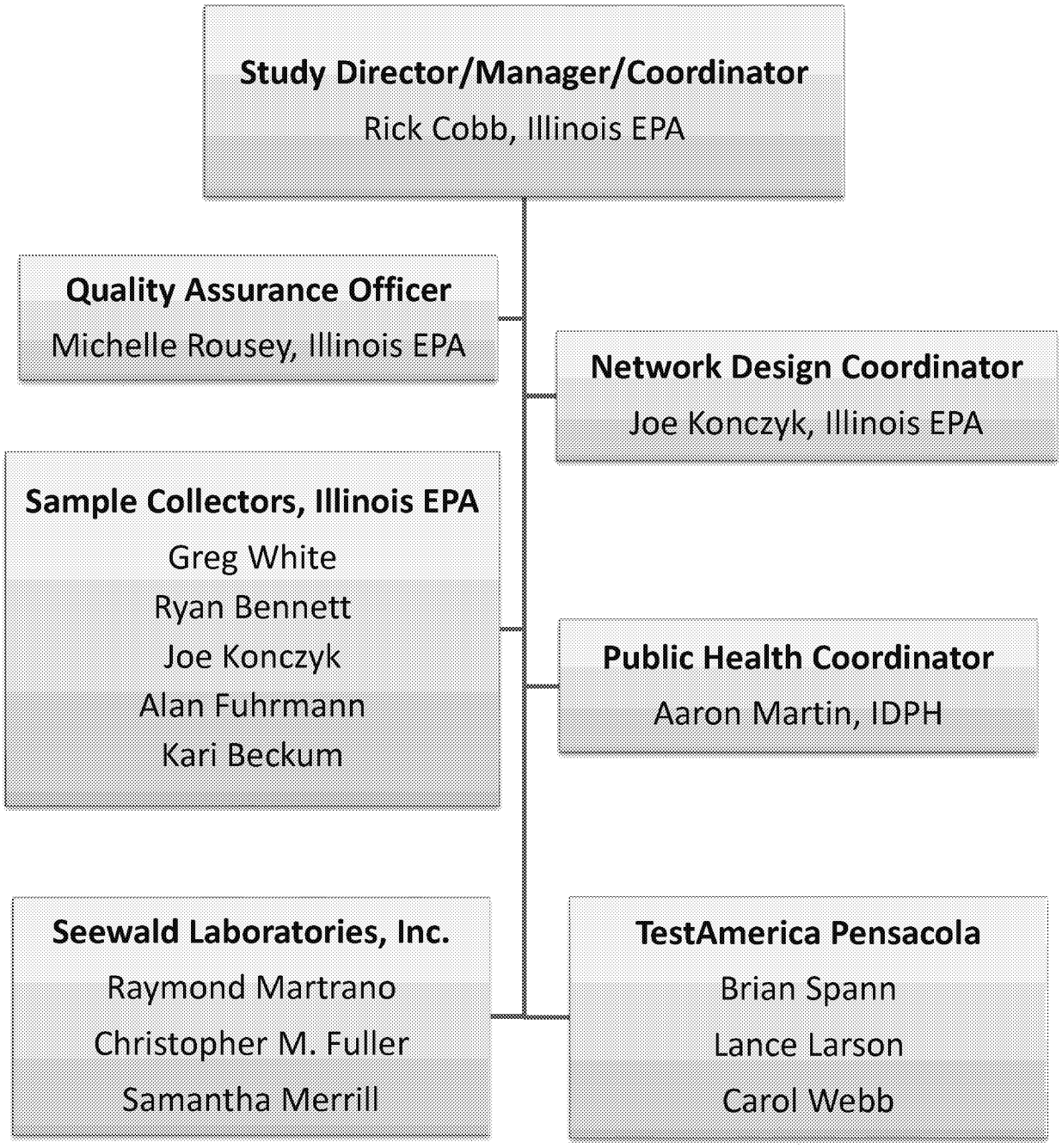
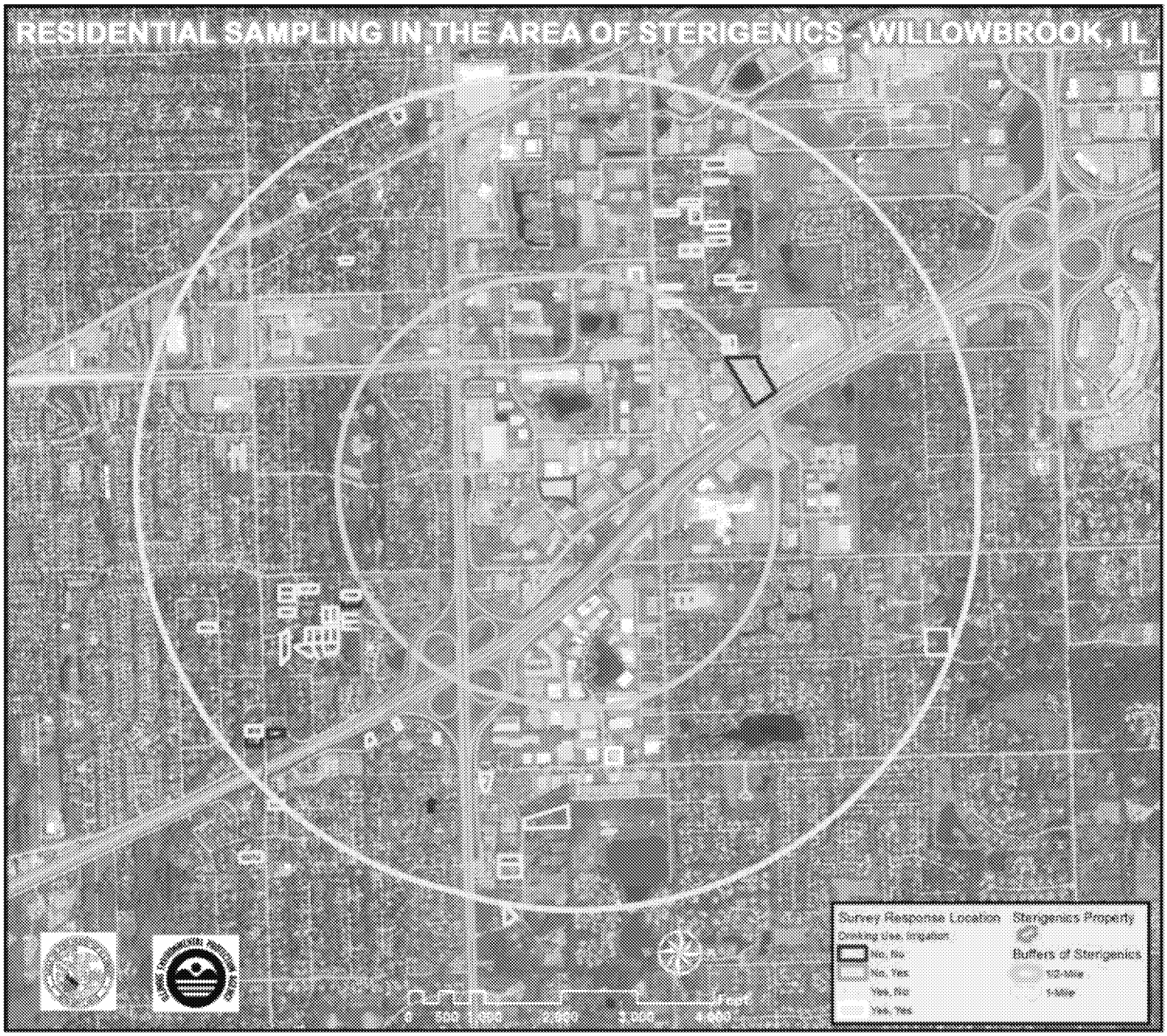


Figure 2 – Map of Residential Sampling Near Sterigenics



TABLES

Table 1 – Study Contact Information

[EMBED Excel.Sheet.8]

Table 2 – Minimum Measurement Criteria and Objectives

Parameter	Minimum Measurement Criteria* mg/L	Minimum Measurement Objectives (MMOs), Reporting Limits (RL) mg/L	Method Detection Limit (MDL) mg/L	Accuracy (% recovery) LCS	Accuracy (Matrix) (% recovery) MS/MSD	Precision (RPD) MS/MSD Duplicates	Completeness (%)
Ethylene Glycol	14	5	3.017	65.6-133	65.6-133	< 26.4%	90
Ethylene Oxide	--	0.025	0.020	50-150	30-160	< 50%	90

LCS = laboratory control sample
MDL = method detection limit
mg/L = milligrams per liter
MMO = minimum measurement objectives
MS = matrix spike
MSD = matrix spike duplicate
RL = reporting limits
RPD = relative percent difference
* Human Threshold Toxicant Advisory Concentration for Class I potable resource groundwater pursuant to Part 620 Groundwater Quality Standards, Subpart F.

Table 3 – Sample Containers, Volumes, Parameters, Method, Preservatives, and Holding Times

Sample Container	Parameter	Method Number	Preservative	Holding Time
Two 40-ml glass VOA vials; Teflon-lined septa cap (Trip blanks: Two 40-ml glass VOA vials)	Ethylene Glycol	USEPA 8015D	Chemical: none Thermal: ≤ 6° C	14 days
Three 40-ml glass VOA vials; Teflon-lined septa cap (Trip blanks: Two 40-ml glass VOA vials)	Ethylene Oxide	USEPA 8260B	Chemical: HCl Thermal: ≤ 6° C	14 days

HCl = hydrochloric acid
ml = milliliter
VOA = volatile organic analysis

Note: The ethylene glycol and ethylene oxide turnaround time from sample receipt to reporting of the sample results is **7 days**.

Table 4 – Standard Operating Procedure and Method for Samples Analyzed at Seewald Laboratories, Inc.

Parameter	Document Number	Title
Ethylene glycol	Organics #19	SOP: Non-Halogenated Organics (Glycols, Alcohols & 2-Butoxyethanol by GC-FID)
Ethylene glycol	USEPA 8015D, Rev. 4 (June 2003)	Method 8015D. Nonhalogenated Organics Using Gas Chromatography/Flame Ionization Detector (GC/FID)

FID = flame ionization detector
GC = gas chromatography

Table 5 – Standard Operating Procedure and Method for Samples Analyzed at TestAmerica Pensacola Laboratory.

Parameter	Document Number	Title
Ethylene oxide	PS-MSV-001, Rev. 20	SOP: Determination of Volatile Organic Compounds
Ethylene oxide	USEPA 8260B, Rev. 2 (December 1996)	Method 8260B. Volatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS)

GC = gas chromatography
MS = mass spectrometry

REFERENCES

U.S. Environmental Protection Agency. May 2001. *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*. (EPA/240/B-01/003). Washington, D.C.

APPENDICES

Appendix A – Private Well Sampling News Release

Appendix B – Illinois EPA Letter to Residents with Private Drinking Water Wells Near Sterigenics

Appendix C – Seewald Laboratories, Inc. Certificate of NELAC Accreditation

Appendix D – TestAmerica Pensacola Laboratory Certificate of NELAC Accreditation

Appendix E – Human Threshold Toxicant Advisory Concentration for Ethylene Glycol

Appendix F – Standard Operating Procedure for Groundwater Sampling

Appendix G – Seewald Laboratories, Inc. Chain of Custody Sheet

Appendix H – TestAmerica Pensacola Laboratory Chain of Custody Sheet

Appendix I – Standard Operating Procedure for the Analysis of Ethylene Glycol

Appendix J – USEPA Method 8015D. Nonhalogenated Organics Using Gas Chromatography/Flame Ionization Detector (GC/FID)

Appendix K – Standard Operating Procedure for the Analysis of Ethylene Oxide

Appendix L – USEPA 8260B. Volatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS)

Appendix M – Quality Assurance Manual for Seewald Laboratories, Inc.

Appendix N – Quality Assurance Manual for TestAmerica Pensacola Laboratory

Appendix A – Private Well Sampling News Release

NEWS RELEASE

FOR IMMEDIATE RELEASE
November 8, 2018

Contact:
Kim Biggs (IEPA) – 217-558-1536
Don Bolger (DCHD) – 630-221-7374

Illinois EPA and DuPage County Health Department to Identify Private Drinking Water Wells Near Sterigenics for Sampling

Water Sampling Plan Under Development to Identify Possible Well Contamination

SPRINGFIELD — Illinois Environmental Protection Agency (EPA) Director Alec Messina and DuPage County Health Department (DCHD) Executive Director Karen Ayala today announced their coordinated effort to identify private wells used for drinking water at homes near the Sterigenics facility in Willowbrook. This is in response to the concerns of residents and local officials of possible groundwater contamination of ethylene glycol from the facility in 2013 and emissions of ethylene oxide. Currently, U.S. EPA has not provided guidance for groundwater analysis for ethylene glycol or ethylene oxide. Therefore, Illinois EPA has established a groundwater health advisory level specific to this sampling exercise. While the potential for contamination appears to be low, a targeted number of drinking water wells will be tested for these chemicals. Illinois EPA and DCHD are taking this important step to ensure the health of residents with these wells near Sterigenics facilities.

"Illinois EPA has listened to the questions and concerns of residents and local officials in Willowbrook and the surrounding area and is committed to conducting private well sampling to provide answers," said Director Messina.

Beginning November 13, Health Department staff will contact homeowners within a one-mile area of Sterigenics to confirm homes with private wells are used for drinking water and ask for permission to collect a sample for testing. Once the wells are identified, Illinois EPA will determine which wells will be sampled. The sampling plan may be expanded outside this area if initial sampling identifies contamination. The sampling and analysis of groundwater from the private wells will be done at NO COST TO HOMEOWNERS.

"Residents want to know if their well water is safe to drink, and so do we. We are working with Illinois EPA to learn as quickly as possible if private wells have been contaminated by ethylene glycol or ethylene oxide," added Karen Ayala, Executive Director of the DuPage County Health Department.

Residents with wells will need to complete an access agreement to allow the collection of a sample from their wells. If residents are not home, an information packet will be left at the front door. In addition, DCHD will send letters to identified property owners, and an online survey and agreement have been developed for residents to provide the necessary information about their private wells, and to allow samples to be taken.

Once the drinking water wells are verified, the water sampling plan will be finalized by Illinois EPA staff. That plan could include up to 200 private wells. Illinois EPA staff will return to the selected homes where access agreements have been completed to take samples. All water samples will be sent to an independent certified laboratory for analysis. The independent sampling and analysis will provide additional information for residents and assist Illinois EPA in identifying groundwater contamination of wells used for drinking water in the area.

Once sampling results are received from the laboratory, the data will be provided to the Illinois Department of Public Health (IDPH), who will provide the sampling results to each of the residents once the results are finalized.

If the groundwater has been contaminated, Illinois EPA officials will share and discuss the information with the Illinois Attorney General's Office. Illinois EPA continues to work cooperatively with the Attorney General's Office to further the case. Both offices are committed to bringing meaningful relief to Willowbrook and surrounding communities.

Appendix B – Illinois EPA Letter to Residents with Private Drinking Water Wells Near Sterigenics

ILLINOIS ENVIRONMENTAL PROTECTION AGENCY
1021 NORTH GRAND AVENUE EAST, P.O. BOX 19276, SPRINGFIELD, ILLINOIS 62794-9276 • (217) 782-3397
BRUCE RAUNER, GOVERNOR ALEC MESSINA, DIRECTOR

Date: November 15, 2018

To: Residents with private water wells in the areas in or near the communities of Willowbrook, Darien and Burr Ridge, Illinois

From: Illinois Environmental Protection Agency – Drinking Water and Groundwater Division

Re: Ground water sampling and testing

Over the coming weeks, the Illinois Environmental Protection Agency–Drinking Water and Groundwater Division is planning to obtain groundwater samples from certain private residential wells used for drinking water in the areas of Willowbrook, Darien and Burr Ridge. The groundwater samples will be tested for ethylene glycol and ethylene oxide in conjunction with other ongoing investigative work associated with the Sterigenics facility located in the Village of Willowbrook. The groundwater sampling and testing is being conducted out of an abundance of caution associated with concerns of residents and local officials regarding potential impacts from the Sterigenics facility.

We ask that you please complete a short survey regarding your well water and provide permission to obtain a ground water sample to be tested at NO COST TO YOU. The Illinois EPA will pay for the sampling and testing. Once testing results are received from the laboratory, the data will be provided to the Illinois Department of Public Health (IDPH), who will provide a letter and interpretation of the sampling results to residents.

Your participation is greatly appreciated.

To complete the survey and provide permission to obtain a ground water sample, please visit: www.dupagehealth.org/wellwatertesting.

If you have questions about the sampling and testing, contact Brad Frost in the Illinois EPA Office of Community Relations at 217-782-7027 or brad.frost@illinois.gov.

Thank you,

Alec Messina
Director
Illinois Environmental Protection Agency

Karen Ayala
Executive Director
DuPage County Health Department

4302 N. Main St., Rockford, IL 61103 (815)987-7760
595 S. State, Elgin, IL 60123 (847)608-3131
2125 S. First St., Champaign, IL 61820 (217)278-5800
2009 Mall St., Collinsville, IL 62234 (618)346-5120
9511 Harrison St., Des Plaines, IL 60016 (847)294-4000
412 SW Washington St., Suite D, Peoria, IL 61602 (309)671-3022
2309 W. Main St., Suite 116, Marion, IL 62959 (618)993-7200
100 W. Randolph, Suite 10-300, Chicago, IL 60601

Appendix C – Seewald Laboratories, Inc. Certificate of NELAC Accreditation

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION

BUREAU OF LABORATORIES

LABORATORY ACCREDITATION PROGRAM

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

Certifies That

41-00034
Seewald Laboratories Inc
2829 Reach Road, Williamsport, PA 17701

Having duly met the requirement of
The act of June 29, 2002 (P.L. 596, No. 90)
dealing with Environmental Laboratories Accreditation
(27 Pa. C.S. §§4104-4113) and the
National Environmental Laboratory Accreditation Program Standard

is hereby approved as an

Accredited Laboratory

to conduct analysis within the fields of accreditations more fully described in the attached Scope of Accreditation

Expiration Date: 01/31/2019
Certificate Number: 017

Aaren S. Alger, Chief
Laboratory Accreditation Program
Bureau of Laboratories

Continued accreditation status depends on successful ongoing participation in the program
Certificate not transferable. Surrender upon revocation
To be conspicuously displayed at the Laboratory
Not valid unless accompanied by a valid Scope of Accreditation
Shall not be used to imply endorsement by the Commonwealth of Pennsylvania
Customers encouraged to verify the laboratory's current accreditation status
PA DEP is a NELAP recognized accreditation body

Appendix D – TestAmerica Pensacola Laboratory Certificate of NELAC Accreditation

STATE OF ILLINOIS
ENVIRONMENTAL PROTECTION AGENCY
NELAP - RECOGNIZED
ENVIRONMENTAL LABORATORY ACCREDITATION

is hereby granted to

TESTAMERICA PENSACOLA
3355 MCLEMORE DRIVE
PENSACOLA, FL 32514
NELAP ACCREDITED
ACCREDITATION NUMBER #200041

According to the Illinois Administrative Code, Title 35, Subtitle A, Chapter II, Part 186, ACCREDITATION OF LABORATORIES FOR DRINKING WATER, WASTEWATER AND HAZARDOUS WASTES ANALYSIS, the State of Illinois formally recognizes that this laboratory is technically competent to perform the environmental analyses listed on the scope of accreditation detailed below.

The laboratory agrees to perform all analyses listed on this scope of accreditation according to the Part 186 requirements and acknowledges that continued accreditation is dependent on successful ongoing compliance with the applicable requirements of Part 186. Please contact the Illinois EPA Environmental Laboratory Accreditation Program (IL ELAP) to verify the laboratory's scope of accreditation and accreditation status. Accreditation by the State of Illinois is not an endorsement or a guarantee of validity of the data generated by the laboratory.

Primary Accrediting Authority: FL Department of Health, Bureau of Laboratories

Celeste M. Crowley
Acting Manager
Environmental Laboratory Accreditation Program

Dave Reed
Accreditation Officer
Environmental Laboratory Accreditation Program

Certificate No.: 004509
Expiration Date: 10/09/2019
Issued On: 09/11/2018

Appendix E – Human Threshold Toxicant Advisory Concentration for Ethylene Glycol

ILLINOIS ENVIRONMENTAL PROTECTION AGENCY
1021 NORTH GRAND AVENUE EAST, P.O. BOX 19276, SPRINGFIELD, ILLINOIS 62794-9276 – (217) 782-3397
JAMES R. THOMPSON CENTER, 100 WEST RANDOLPH, SUITE 11-300, CHICAGO, IL 60601 – (312) 814-6026
ROD R. BLAGOJEVICH, GOVERNOR DOUGLAS P. SCOTT, DIRECTOR

MEMORANDUM

DATE: January 5, 2007 **Revision 1**

TO: HTTAC File

FROM: Tom Hornshaw BY: Michelle Rousey MRR

SUBJECT: Class I Cleanup Objective Recommendation

Ethylene Glycol **(CAS #107-21-1)**

CONFIDENTIAL

NOTE: This memo replaces the memo of February 8, 1990 to delete an analytical test method which is no longer valid.

On March 17, 2006, the Toxicity Assessment Unit (TAU) was asked to recommend a groundwater cleanup objective for ethylene glycol. Due to the lack of a groundwater standard or final MCLG for ethylene glycol, the determination of a cleanup objective recommendation was referred to the TAU.

The cleanup objective has been calculated using a chronic oral Reference Dose (RfD). The RfD is an estimate of the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD for ethylene glycol was developed based upon the occurrence of kidney toxicity in rats after oral exposure. It has been used to calculate an Acceptable Daily Exposure (ADE) and a Human Threshold Toxicant Advisory Concentration (HTTAC), using the Groundwater Quality Standards, Subpart F methodologies and assumptions. The RfD value of 2 mg/kg/day was obtained through the USEPA's on-line Integrated Risk Information System (IRIS). IRIS was accessed on 1/3/07.

Assumptions

Per Capita Daily Water Consumption: 2 liters/day
Body Weight: 70 kg
Exposure Duration: Lifetime (70 years)
Relative Source Contribution: 20%

ROCKFORD – 4302 North Main Street, Rockford, IL 61103 – (815) 987-7760 • DES PLAINES – 9511 W. Harrison St., Des Plaines, IL 60016 – (847) 294-4000
ELGIN – 595 South State, Elgin, IL 60123 – (847) 608-3131 • PEORIA – 5415 N. University St., Peoria, IL 61614 – (309) 693-5463
BUREAU OF LAND – PEORIA – 7620 N. University St., Peoria, IL 61614 – (309) 693-5462 • CHAMPAIGN – 2125 South First Street, Champaign, IL 61820 – (217) 278-5800
SPRINGFIELD – 4500 S. Sixth Street Rd., Springfield, IL 62706 – (217) 786-6892 • COLLINSVILLE – 2009 Mall Street, Collinsville, IL 62234 – (618) 346-5120
MARION – 2309 W. Main St., Suite 116, Marion, IL 62959 – (618) 993-7200

Calculations

ADE = 2 mg/kg/day x 70 kg = 140 mg/day

$$\text{HTTAC} = \frac{140 \text{ mg/day}}{2 \text{ l/day}} \times 0.2 = 14 \text{ mg/l}$$

The recommended class I **groundwater objective is 14 mg/l.**

Estimated Quantitation Limit (EQL)

The EQL for ethylene glycol in groundwater is not available from the SW846 methods.

F:\TOX MEMOS\OBJREQ\ethylene glycol httac07.doc

Appendix F – Standard Operating Procedure for Groundwater Sampling

Illinois Environmental Protection Agency
Bureau of Water

Document Control Number 226

Standard Operating Procedure for

Groundwater Sampling

Division of Public Water Supplies
Groundwater Section
1021 North Grand Avenue East
P.O. Box 19276
Springfield, Illinois 62794-9276

Approved:

_____ _____
Anthony Dulka — Date
IEPA Bureau of Water, PWS Planning & Assessment Unit Supervisor

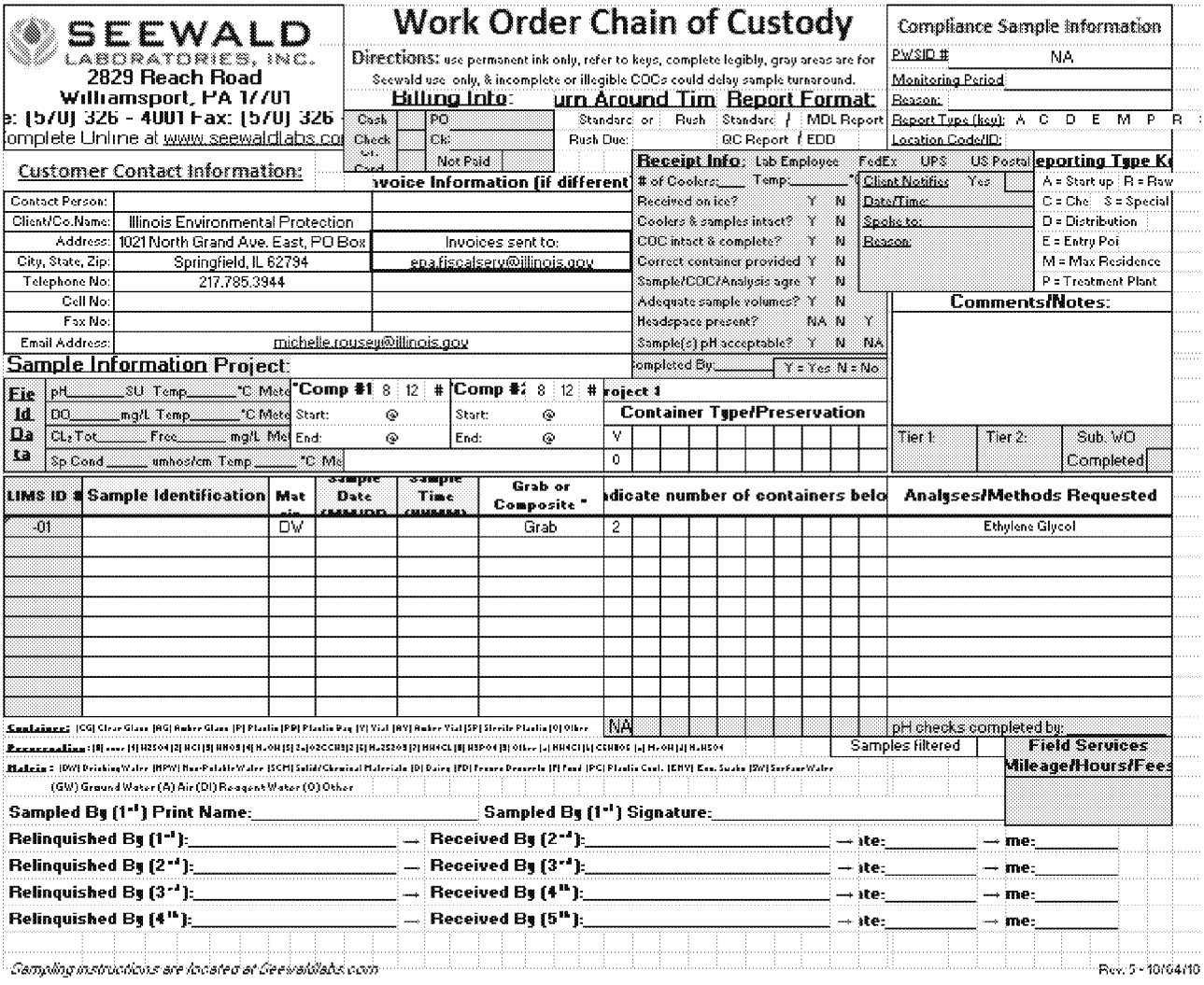
_____ _____
Michelle Rousey — Date
IEPA Bureau of Water, Quality Assurance Officer

Annual Review (no changes):

	2016	2017	2018	2019	2020
Initials/Date					Full review and approval needed
Initials/Date					

NOTE: A copy of the full SOP is being stored in a secure location by the Illinois EPA's Bureau of Water QAO as it may contain confidential and proprietary information.

Appendix G – Seewald Laboratories, Inc. Chain of Custody Sheet



SEEWALD LABORATORIES, INC.
2829 Reach Road
Williamsport, PA 17701
e: (570) 326 - 4001 Fax: (570) 326 -
omplete Online at www.seewaldlabs.co

Work Order Chain of Custody

Directions: use permanent ink only, refer to keys, complete legibly, gray areas are for Seewald use only, & incomplete or illegible COCs could delay sample turnaround.

Billing Info: urn Around Tim Report Format:

Cash | PO
Check | Ck:
Cr. Card | Not Paid

Standard or Rush | Standard / MDL Report
Rush Due: | QC Report / EDD

Compliance Sample Information
PWSID #: NA
Monitoring Period:
Reason:
Report Type (low): A C D E M P R
Location Code/ID:

Customer Contact Information:

Contact Person:	
Client/Co.Name:	Illinois Environmental Protection
Address:	1021 North Grand Ave. East, PO Box
City, State, Zip:	Springfield, IL 62794
Telephone No:	217.785.3944
Cell No:	
Fax No:	
Email Address:	michelle.rousey@illinois.gov

Invoice Information (if different)
Invoices sent to: epa.fiscalserv@illinois.gov

Receipt Info: Lab Employee | FedEx | UPS | US Postal
# of Coolers: Temp: °C
Client Notified: Yes
Received on ice? Y N
Date/Time:
Coolers & samples intact? Y N
Spoke to:
COC intact & complete? Y N
Reason:
Correct container provided Y N
Sample/COC/Analysis agre Y N
Adequate sample volumes? Y N
Headspace present? NA N Y
Sample(s) pH acceptable? Y N NA
Completed By: Y = Yes N = No

Reporting Type K
A = Start up R = Rew
C = Che S = Special
D = Distribution
E = Entry Poi
M = Max Residence
P = Treatment Plant

Comments/Notes:

Sample Information Project:

Field Data: pH SU Temp °C Mete; DO mg/L Temp °C Mete; CL2 Tot Free mg/L Me; Sp Cond umhos/cm Temp °C Me

Comp #1 8 12 # Start: @ End: @
Comp #2 8 12 # Start: @ End: @
Project 1

Container Type/Preservation

Tier 1: | Tier 2: | Sub. WO Completed

LIMS ID #	Sample Identification	Matrix	Sample Date (mm/dd/yy)	Sample Time (military)	Grab or Composite *	Indicate number of containers belo	Analyses/Methods Requested
-01		DW			Grab	2	Ethylene Glycol

Containers: [CG] Clear Glass [AG] Amber Glass [P] Plastic [PP] Plastic Pag [V] Vial [AV] Amber Vial [SP] Sterile Plastic [O] Other

Preservation: [0] none [1] H2SO4 [2] HCl [3] HNO3 [4] H2OH [5] Na2O2CH3)2 [6] H2SO3 [7] HNaCL [8] H3PO4 [9] Other [A] HNaCl [B] CSNaOS [a] H2OH [J] H2SO4

Matrix: [DW] DrinkingWater [NPW] NonPotableWater [SCM] SolidChemicalMaterials [D] Dairy [FD] Frozen Desserts [F] Food [PC] Plastic Cont. [ENV] Env. Swabs [SW] SurfaceWater (GW) Ground Water (A) Air (DI) Reagent Water (O) Other

NA | pH checks completed by:

Samples filtered

Field Services Mileage/Hours/Fees

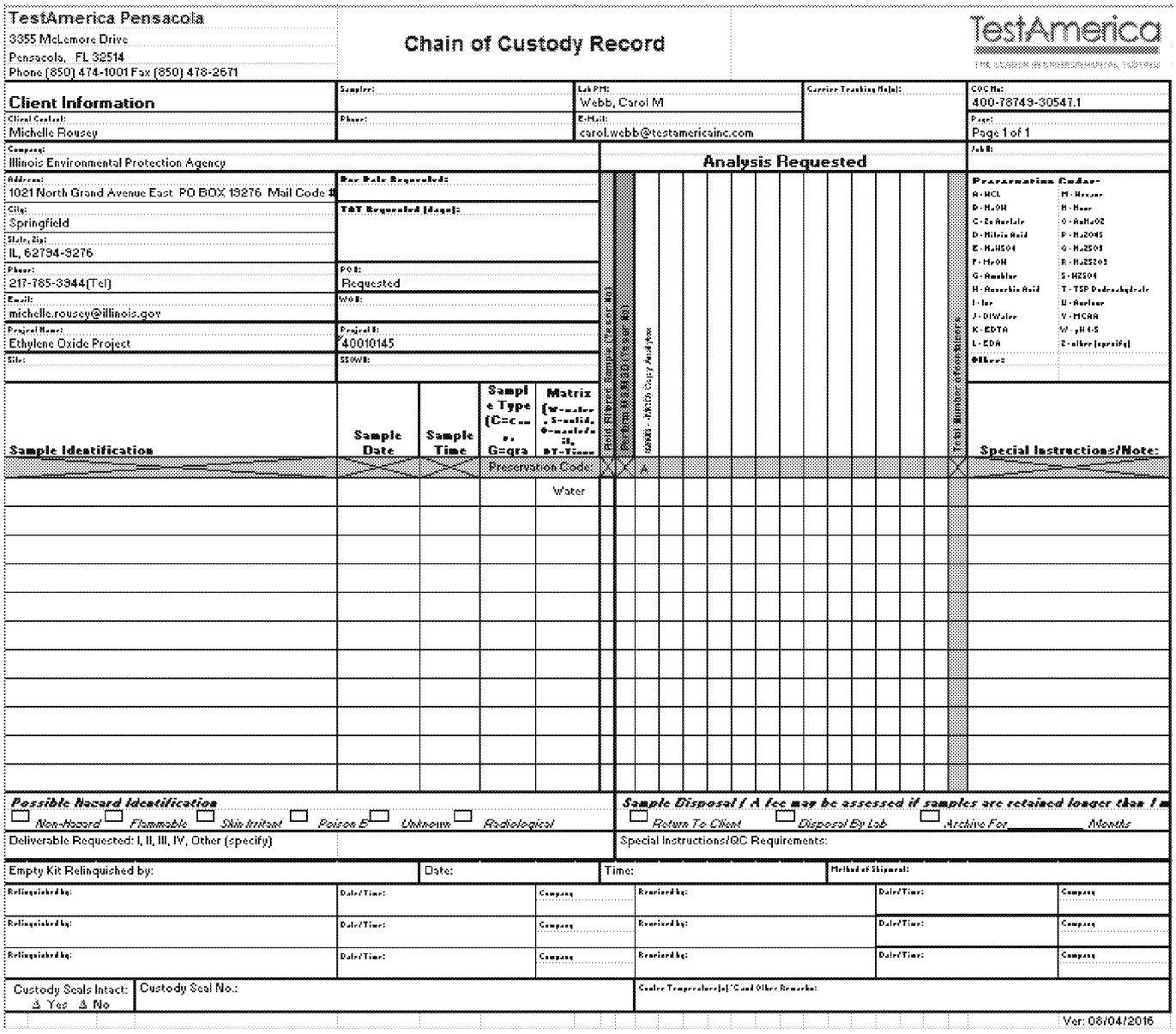
Sampled By (1st) Print Name: Sampled By (1st) Signature:

Relinquished By (1st): Received By (2nd): Date: Time:
Relinquished By (2nd): Received By (3rd): Date: Time:
Relinquished By (3rd): Received By (4th): Date: Time:
Relinquished By (4th): Received By (5th): Date: Time:

Sampling instructions are located at Seewaldlabs.com

Rev. 5 - 10/04/10

Appendix H – TestAmerica Pensacola Laboratory Chain of Custody Sheet



TestAmerica Pensacola
3355 McLemore Drive
Pensacola, FL 32514
Phone (850) 474-1001 Fax (850) 478-2671

Chain of Custody Record

TestAmerica

Client Information	Sampler:	Lab PM: Webb, Carol M	Carrier Tracking No(s):	COC No: 400-78749-30547.1
Client Contact: Michelle Rousey	Phone:	E-Mail: carol.webb@testamericainc.com		Page: Page 1 of 1
Company: Illinois Environmental Protection Agency		**Analysis Requested**		Job #:
Address: 1021 North Grand Avenue East PO BOX 19276 Mail Code #	Due Date Requested:			Preservation Codes: A - HCL, B - NaOH, C - Zn Acetate, D - Nitric Acid, E - NaHSO4, F - MeOH, G - Amchlor, H - Ascorbic Acid, I - Ice, J - DI Water, K - EDTA, L - EDA, M - Hexane, N - Na2O4S, O - NaNO3, P - Na2O4S, Q - Na2SO3, R - Na2S2O3, S - H2SO4, T - TSP Dodecahydrate, U - Acetone, V - MCAA, W - pH 4-5, Z - other (specify)
City: Springfield	TAT Requested (days):			
State, Zip: IL, 62794-9276	PO #: Requested			
Phone: 217-785-3944(Tel)	WO #:			
Email: michelle.rousey@illinois.gov	Project #: 40010145			
Project Name: Ethylene Oxide Project	SSOW#:			
Site:				Other:

Sample Identification	Sample Date	Sample Time	Sample Type (C=comp, G=grab)	Matrix (W=water, S=solid, O=waste/oil, BT=Tissue)	Field Filtered Sample (Yes or No)	Perform MS/MSD (Yes or No)	624/8021 - HVOCs Copy Analysis	Total Number of Containers	Special Instructions/Note:
			Preservation Code:		X	X	A	X	
				Water					

Possible Hazard Identification
☐ Non-Hazard ☐ Flammable ☐ Skin Irritant ☐ Poison B ☐ Unknown ☐ Radiological

Sample Disposal (A fee may be assessed if samples are retained longer than 1 m
☐ Return To Client ☐ Disposal By Lab ☐ Archive For _____ Months

Deliverable Requested: I, II, III, IV, Other (specify)

Special Instructions/QC Requirements:

Empty Kit Relinquished by:	Date:	Time:	Method of Shipment:

Relinquished by:	Date/Time:	Company	Received by:	Date/Time:	Company
Relinquished by:	Date/Time:	Company	Received by:	Date/Time:	Company
Relinquished by:	Date/Time:	Company	Received by:	Date/Time:	Company

Custody Seals Intact: ☐ Yes ☐ No | Custody Seal No.: | Cooler Temperature(s) °C and Other Remarks:

Ver: 08/04/2016

Appendix I – Standard Operating Procedure for the Analysis of Ethylene Glycol

2629 Reach Road
Williamsport, PA 17701
Phone: (570) 326 - 4081

Fax: (570) 326 - 6399
www.seewaldlabs.com

Document No: Organics # 19
Method: EPA 8015 D
Edition/Revision: rev. 4 – 6/2003
Effective Date: January 7, 2011

Revision Date: November 14, 2018
SOP Revision No: 11

Non-Halogenated Organics

(Glycols, Alcohols & 2-Butoxyethanol by GC-FID)

1. **Identification of Test Method.**
   a. This Standard Operating Procedure has been adopted from the Methods for Chemical Analysis of Water and Wastes EPA 8015 D rev. 4 – June 2003 and is used for the determination of Non-Halogenated Organics.
   b. The technology is automated liquid sampler (ALS) direct aqueous injection coupled with gas chromatography and flame ionization detector (GC-FID).
   c. The results are then determined using Hewlett Packard ChemStation software by summation of the detected compounds and reported as the total.
   d. This method is restricted for use by or under the supervision of analysts experienced in the determination and interpretation of organic compounds by gas chromatography or equivalent technologies. In addition, this method is to be used for the analysis of non-halogenated organic compounds, its use should be limited to analysts experienced in the interpretation of organics data.
   e. This Standard Operating Procedure (SOP) states Seewald Laboratories, Inc.'s policies and procedures established in order to meet requirements of all its certifications and/or accreditations currently maintained, including The NELAC Institute (TNI) most recent standard.
   f. This SOP is applicable to the most recent revision of the base method. However, other method revisions may be analyzed and reported by this SOP due to the fact that the most stringent of all method revision's quality control requirements are performed and acceptable unless otherwise qualified.

Printed: 11/19/18 at 15:29

NOTE: A copy of the full SOP is being stored in a secure location by the Illinois EPA's Bureau of Water QAO as it may contain confidential and proprietary information.

Appendix J – USEPA Method 8015D. Nonhalogenated Organics Using Gas Chromatography/Flame Ionization Detector (GC/FID)

METHOD 8015D

NONHALOGENATED ORGANICS USING GC/FID

1.0 SCOPE AND APPLICATION

1.1 This method may be used to determine the concentrations of various nonhalogenated volatile organic compounds and semivolatile organic compounds by gas chromatography. The following compounds have been determined quantitatively by this method, using the preparative techniques indicated.

Compound	CAS No.[a]	Appropriate Technique				
		Purge-and-Trap[b]	Head-space[c]	Direct Aqueous Injection	Azeo. Dist.[c]	Vacuum Dist.[d]
Acetone	67-64-1	pp / ht	x	x	x	x
Acetonitrile	75-05-8	pp	ne	x	x	ne
Acrolein	107-02-8	pp	ne	x	x	x
Acrylonitrile	107-13-1	pp	ne	x	x	x
Allyl alcohol	107-18-6	ht	ne	x	x	ne
t-Amyl alcohol (TAA)	75-85-4	ht	x	ne	ne	x
t-Amyl ethyl ether (TAEE)	919-94-8	x/ ht	x	ne	ne	x
t-Amyl methyl ether (TAME)	994-05-8	x/ ht	x	ne	ne	x
Benzene	71-43-2	x	x	ne	ne	x
t-Butyl alcohol (TBA)	75-65-0	ht	x	x	x	x
Crotonaldehyde	123-73-9	pp	ne	x	x	ne
Diethyl ether	60-29-7	x	ne	x	ne	ne
Diisopropyl ether (DIPE)	108-20-3	x/ ht	x	ne	ne	x
Ethanol	64-17-5	i	x	x	x	x
Ethyl acetate	141-78-6	i	x	x	x	ne
Ethyl Benzene	100-41-4	x	x	ne	ne	x
Ethylene oxide	75-21-8	i	ne	x	x	ne
Ethyl *tert*-butyl ether (ETBE)	637-92-3	x/ ht	x	ne	ne	x
Isopropyl alcohol (2-Propanol)	67-63-0	pp	x	x	x	ne
Methanol	67-56-1	i	x	x	x	ne
Methyl ethyl ketone (MEK, 2-Butanone)	78-93-3	pp	x	x	x	x
Methyl *tert*-butyl ether (MTBE)	1634-04-4	x/ ht	x	x	ne	x
N-Nitroso-di-*n*-butylamine	924-16-3	pp	ne	x	x	ne
Paraldehyde	123-63-7	pp	ne	x	x	ne
2-Pentanone	107-87-9	pp	x	x	x	ne
2-Picoline	109-06-8	pp	ne	x	x	ne
1-Propanol (*n*-Propyl alcohol)	71-23-8	pp	x	x	x	ne
Propionitrile	107-12-0	ht	ne	x	x	ne
Pyridine	110-86-1	i	ne	x	x	ne
Toluene	108-88-3	x	x	ne	ne	x

Note: A copy of the full method may be obtained online or by contacting the Illinois EPA's Bureau of Water QAO.

Appendix K – Standard Operating Procedure for the Analysis of Ethylene Oxide

TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING

Pensacola

SOP No. PS-MSV-001, Rev. 20
Effective Date: 06/25/2018
Page No.: 1 of 110

Title: Determination of Volatile Organic Compounds [SW-846 8260B/C, EPA 624/624.1, SM 6200B, CLP OLM03.1, MO GRO, and the Determination of Total Dithiocarbamates as Carbon Disulfide]

Approvals (Signature/Date):

Shelley R. Kearley 06/25/2018
Shelley Kearley Date
Department Manager

Lance Larson 06/25/2018
Lance Larson Date
Quality Assurance Manager

Daniel Waite 06/25/2018
Daniel Waite Date
Technical Director

Facility Distribution No. PS-MSV-001 Distributed To: CONTROLLED SOPS

Only Electronic Copies are Controlled.

NOTE: A copy of the full SOP is being stored in a secure location by the Illinois EPA's Bureau of Water QAO as it may contain confidential and proprietary information.

Appendix L – USEPA 8260B. Volatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS)

METHOD 8260B
VOLATILE ORGANIC COMPOUNDS BY GAS CHROMATOGRAPHY/
MASS SPECTROMETRY (GC/MS)

1.0 SCOPE AND APPLICATION

1.1 Method 8260 is used to determine volatile organic compounds in a variety of solid waste matrices. This method is applicable to nearly all types of samples, regardless of water content, including various air sampling trapping media, ground and surface water, aqueous sludges, caustic liquors, acid liquors, waste solvents, oily wastes, mousses, tars, fibrous wastes, polymeric emulsions, filter cakes, spent carbons, spent catalysts, soils, and sediments. The following compounds can be determined by this method:

		Appropriate Preparation Technique[a]					
Compound	CAS No.[a]	5030/ 5035	5031	5032	5021	5041	Direct Inject.
Acetone	67-64-1	pp	c	c	nd	c	c
Acetonitrile	75-05-8	pp	c	nd	nd	nd	c
Acrolein (Propenal)	107-02-8	pp	c	c	nd	nd	c
Acrylonitrile	107-13-1	pp	c	c	nd	c	c
Allyl alcohol	107-18-6	ht	c	nd	nd	nd	c
Allyl chloride	107-05-1	c	nd	nd	nd	nd	c
Benzene	71-43-2	c	nd	c	c	c	c
Benzyl chloride	100-44-7	c	nd	nd	nd	nd	c
Bis(2-chloroethyl)sulfide	505-60-2	pp	nd	nd	nd	nd	c
Bromoacetone	598-31-2	pp	nd	nd	nd	nd	c
Bromochloromethane	74-97-5	c	nd	c	c	c	c
Bromodichloromethane	75-27-4	c	nd	c	c	c	c
4-Bromofluorobenzene (surr)	460-00-4	c	nd	c	c	c	c
Bromoform	75-25-2	c	nd	c	c	c	c
Bromomethane	74-83-9	c	nd	c	c	c	c
n-Butanol	71-36-3	ht	c	nd	nd	nd	c
2-Butanone (MEK)	78-93-3	pp	c	c	nd	nd	c
t-Butyl alcohol	75-65-0	pp	c	nd	nd	nd	c
Carbon disulfide	75-15-0	pp	nd	c	nd	c	c
Carbon tetrachloride	56-23-5	c	nd	c	c	c	c
Chloral hydrate	302-17-0	pp	nd	nd	nd	nd	c
Chlorobenzene	108-90-7	c	nd	c	c	c	c
Chlorobenzene-d_5 (IS)		c	nd	c	c	c	c
Chlorodibromomethane	124-48-1	c	nd	c	nd	c	c
Chloroethane	75-00-3	c	nd	c	c	c	c
2-Chloroethanol	107-07-3	pp	nd	nd	nd	nd	c
2-Chloroethyl vinyl ether	110-75-8	c	nd	c	nd	nd	c
Chloroform	67-66-3	c	nd	c	c	c	c
Chloromethane	74-87-3	c	nd	c	c	c	c
Chloroprene	126-99-8	c	nd	nd	nd	nd	c
3-Chloropropionitrile	542-76-7	l	nd	nd	nd	nd	pc

(continued)

Note: A copy of the full method may be obtained online or by contacting the Illinois EPA's Bureau of Water QAO.

Appendix M – Quality Assurance Manual for Seewald Laboratories, Inc.

SEEWALD
LABORATORIES, INC.

QUALITY ASSURANCE MANUAL

2829 Reach Road

Williamsport, PA 17701

Phone: (570) 326 – 4001 • Fax: (570) 326 – 0399

"Providing quality analytical services since 1939"

www.seewaldlabs.com

The NELAC Institute Number: TNI 02269

EPA Lab ID: 00070 • Pennsylvania Lab ID: 41-00034

PADWIS Number: 41034 • Food and Drug Administration ID: 42-B-00142

Maryland Lab ID: 202 • State of Delaware – Office of Drinking Water

New York State Department of Health Lab ID: 12028

US Food & Drug Administration Registered

This Quality Assurance Manual revision has been read, verified, and is approved for the scope, volume, and range of testing by the Owner and Directors of Seewald Laboratories, Inc. with the following laboratory approved signatories on *November 13, 2018*.

Laboratory Owner: _____ (Mr. Robert Channell)

Laboratory Director: _____ (Mr. Raymond I. Mantano)

Quality Director: _____ (Mr. Christopher M. Fuller)

Dairy Lab Director: _____ (Ms. Elizabeth Fischer)

NOTE: A copy of the full Quality Assurance Manual is being stored in a secure location by the Illinois EPA's Bureau of Water QAO as it may contain confidential and proprietary information.

Appendix N – Quality Assurance Manual for TestAmerica Pensacola Laboratory

TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING

Document No. PS-QAM-001
Revision No. : 11
Effective Date: 03/01/2018
Page 1 of 179

Quality Assurance Manual

TestAmerica Pensacola
3355 McLemore Dr.
Pensacola, Fl 32514
850-474-1001
850-478-2671
www.testamericainc.com

Facility Distribution No. PS-QAM-001 Distributed To: CONTROLLED SOP's\QAM

NOTE: A copy of the full Quality Assurance Manual is being stored in a secure location by the Illinois EPA's Bureau of Water QAO as it may contain confidential and proprietary information.

NEWS RELEASE

FOR IMMEDIATE RELEASE
December 10, 2018

Contact:
Kim Biggs (IEPA) – 217-558-1536
Don Bolger (DCHD) – 630-221-7374

DRAFT

Private Drinking Water Wells Near Sterigenics Facility to be Sampled this Week

Private Well Sampling Being Conducted to Identify Possible Well Contamination

SPRINGFIELD — Illinois Environmental Protection Agency (EPA) Director Alec Messina and DuPage County Health Department (DCHD) Executive Director Karen Ayala today announced the start of groundwater sampling near the Sterigenics facility in Willowbrook. Illinois EPA and DCHD have worked closely to identify private wells, obtain access agreements and develop a thorough sampling plan. A Quality Assurance Project Plan has been developed by Illinois EPA technical staff and reviewed by DCHD staff. The plan includes all ~~62~~ 1 homes. Fifty-eight (58) are located within a one-mile radius of the facility and 3 well are just beyond the 1-mile radius, where access agreements were signed. While the potential for contamination appears to be low, each of drinking water wells will be tested for ethylene oxide and ethylene glycol. Illinois EPA and DCHD remain committed to ensuring the health of residents with drinking water wells.

Commented [CR1]:

Beginning December ~~11~~ 12, Illinois EPA staff will take water samples from homes previously identified by the canvassing efforts of the DuPage County Health Department. Health Department staff will accompany Illinois EPA staff to answer any questions homeowners may have about private drinking water wells. Well sampling will primarily be done by collecting water samples from outside spickets from homes identified. This will prevent staff from having to enter homes.

All water samples will be sent to an independent certified laboratory for analysis for ethylene oxide and ethylene glycol. The independent sampling and analysis will provide additional information for residents and assist Illinois EPA in identifying groundwater contamination of wells used for drinking water in the area. The sampling plan may be expanded outside the one-mile radius if initial sampling identifies contamination. The sampling and analysis of groundwater from the private wells is being done at **NO COST TO HOMEOWNERS.**

Once sampling results are received from the laboratory, the data will be provided to the Illinois Department of Public Health (IDPH), who will provide the sampling results to each of the residents once the results are finalized.

2/DuPage County Private Well Sampling

###

Message

From: Jennifer McConahy **Personal Email / Ex. 6**
Sent: 5/8/2019 10:47:04 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Letter
Attachments: State of IL County of DuPage v. Sterigenics 18 CH 1329 (DuPage County) 050319.pdf

FYI

https://www.willowbrookil.org/DocumentCenter/View/1581

Message

From: Jennifer McConahy **Personal Email / Ex. 6**
Sent: 2/25/2019 9:48:24 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Timeline of ethylene oxide, chemical at center of suburban pollution controversy - Chicago Tribune

Timeline of ethylene oxide, chemical at center of suburban pollution controversy - Chicago Tribune

https://www.chicagotribune.com/news/ct-sterigenics-eto-timeline-htmlstory.html

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 5/29/2019 1:44:41 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: FYI
Attachments: Sterigenics+EO+Sources+Release+5.29.19.pdf

https://static1.squarespace.com/static/5b8457322714e5cbd33c889a/t/5cee5844e2c48339d863aacd/1559124036645/Sterigenics+EO+Sources+Release+5.29.19.pdf

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 5/29/2019 1:44:21 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: FYI
Attachments: Sterigenics+Letter+to+EPA+re+Ambient+results+10MAY2019.pdf

https://static1.squarespace.com/static/5b8457322714e5cbd33c889a/t/5cee58184e17b6215b12dfa0/1559123993278/Sterigenics+Letter+to+EPA+re+Ambient+results+10MAY2019.pdf

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 3/5/2019 2:29:50 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: You have probably seen but passing along
Attachments: Sterigenics-Head-Met-Repeatedly-With-EPA-Over-Toxic-Carcinogen.pdf

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 2/24/2019 4:04:00 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Air Pollution Crisis in Willowbrook, Ill., Exposes Toxic Racial Divide

Air Pollution Crisis in Willowbrook, Ill., Exposes Toxic Racial Divide

https://theintercept.com/2019/02/24/epa-response-air-pollution-crisis-toxic-racial-divide/

Message

From: Jennifer McConahy [Personal Email / Ex. 6]
Sent: 2/25/2019 2:20:52 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Calendar for Bill Wehrum, Assistant Administrator for the Office of Air and Radiation | Senior Leaders' Calendars | US EPA

Does anyone know why he is having so many phone calls with sterigenics? And what the eto meeting on the hill was?

Calendar for Bill Wehrum, Assistant Administrator for the Office of Air and Radiation | Senior Leaders' Calendars | US EPA

https://www.epa.gov/senior-leaders-calendars/calendar-bill-wehrum-assistant-administrator-office-air-and-radiation

Message

From: Jennifer McConahy [redacted] **Personal Email / Ex. 6**
Sent: 2/8/2019 5:19:17 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Attachments: Call for Sterigenics Shutdown FIN (Media Advisory).docx

Message

From: Jennifer McConahy **Personal Email / Ex. 6**
Sent: 2/13/2019 5:22:46 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Wow! What does this mean? Anything?
Attachments: 19.02.13 - Wheeler Sterigenics.pdf

https://www.duckworth.senate.gov/imo/media/doc/19.02.13%20-%20Wheeler%20Sterigenics.pdf

Message

From: Jennifer McConahy **Personal Email / Ex. 6**
Sent: 2/12/2019 11:48:28 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Suburban towns join lawsuits against Sterigenics and urge Illinois attorney general to shut company down - The Doings Weekly

Suburban towns join lawsuits against Sterigenics and urge Illinois attorney general to shut company down - The Doings Weekly

https://www.chicagotribune.com/suburbs/burr-ridge/news/ct-dhd-sterigenics-towns-respond-tl-0214-story.html
https://www.chicagotribune.com/suburbs/burr-ridge/news/ct-dhd-sterigenics-towns-respond-tl-0214-story,amp.html?__twitter_impression=true&fbclid=IwAR0uF51J8G6B7Pntxgfukdp0bquZ0cgXdlC0hA9PWZMnDuBmPAbgq1dfLVQ

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 2/11/2019 6:58:22 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: questions

Hi Laura-

A few questions for you if you have a minute

1. Were you able to get the information the EPA needed from Sterigenics last week?

2. Why hasn't there been any more stack testing completed? It was thought to be incomplete when completed in the fall. Tested by a company Sterigenics hired.... enough said.

3. When will more air monitoring data results be posted?

4. What is the EPA's response to our congressman Lipinskis press conference?

Thank you-
Jen

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 12/20/2018 8:05:29 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Questions

Hi Laura-
Can you tell me who answers the questions and if sterigenics was involved in providing answers? Or anyone involved in yhe EOSA?
Overall I am very disappointed by these answers
Jen

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 2/4/2019 4:54:52 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: https://cbsloc.al/2D4HpfX

https://cbsloc.al/2D4HpfX

Hi Laura-
I would encourage you and everyone working on the Sterigenics issue to watch this segment that aired yesterday. It's terribly alarming and for the life of me I can't digure out why they remain open.
Jen

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 1/31/2019 6:39:25 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: update

Hi Laura,

I realize you are only a few days into catching up on over a months work of work and issues. I was wondering when we could expect air monitoring results to be posted. I saw the there was an update 1/28 indicating they should be posted soon,

I know that Mr. Wehrum thought that there would be another meeting with the EPA (coming to Willowbrook) as soon as February. Has there been any date or timeframe discussed?

Where do things stand with more testing of Sterigenics facility? There clearly is some controversy around this issue.

OIG progress?

If you have any updates or other info you could pass along, I would appreciate it. We are beyond frustrated with the lack of progress since December and have run into frightening roadblocks with all the lawmakers finding potential corruption, secrets and allowing industry to call the shots.

Thanks for your help-
Jen

Message

From: Jennifer McConahy [Personal Email / Ex. 6]
Sent: 12/19/2018 1:48:32 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: IEPA knew of Excessive Risk around Sterigenics

IEPA knew of Excessive Risk around Sterigenics

Hot off the press this morning. Please tell me how this facility is still open?

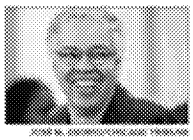
https://www.stopsterigenics.com/blog/iepa-knew-of-excessive-risk-around-sterigenics

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 12/23/2018 7:34:35 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Sunday, headlining article about Willowbrook problem

Chicago Tribune

Sunday, December 16, 2018



Cook County Board President Toni Preckwinkle is also head of the county's Democratic Party.

Alderman to county boss to mayor?

Preckwinkle opposed machine, worked with it, became 'progressive'

By Hal Dardick
Chicago Tribune

When Cook County Democrats began cast 45 years ago to pick a new leader, a coalition of liberal, mostly white, mostly suburban men assembled inside their old, smoke-filled local headquarters at Clark and Madison to support then-County Clerk Richard J. Daley as chairman of an organization backed by party regulars.

The optics were poor. Selected in April, as party officials often gathered to elect a leader, a lineup lot of men and women, some casually dressed, sniffed about an open, contemporary convention room in a high-rise at

Turn to Preckwinkle, Page 8

Shutdown to stretch past Christmas

As Trump clings to wall demand, legislators leave D.C., workers in limbo

By Lisa Mascaro, Barbara Sprunt and Kevin Freking
Associated Press

WASHINGTON — The partial federal shutdown was expected to drag past Christmas as President Donald Trump and congressional leaders remained stuck in a standoff over his border wall with Mexico with no breakthrough Saturday.

Vice President Mike Pence arrived on Capitol Hill with a counteroffer to Democrats after the sides traded offers in several days.

At the White House, Trump

Turn to Shutdown, Page 10

Chemical's public health impact just becoming clear

Insiders knew of ethylene oxide's ties to cancer. Waukegan and Willowbrook didn't.

By Michael Hawthorne
Chicago Tribune

When Julie Carroll was born in the 1960s, the Sterigenics plant in Willowbrook churned up to 300,000 pounds of cancer-causing ethylene oxide into the air every year.

Carroll grew up about a mile from the facility in a leafy suburban neighborhood of big homes and even bigger yards. She attended public schools close to Sterigenics. But like most residents of the DuPage County village, she had no idea the company existed until this summer, when the U.S. Environmental Protection Agency singled out Willowbrook as one of a few dozen communities across the nation facing alarmingly high cancer risks from toxic air pollution.

Diagnosed with breast cancer in 2016, shortly after her 30th birthday, Carroll endured a double mastectomy and rounds of debilitating radiation and chemotherapy. Now she is among dozens of cancer survivors and families of victims wondering if daily exposure to an obscure industrial chemical contributed to their diseases.

"My parents moved to Willowbrook because my dad felt like we

Turn to Chemical, Page 12

Officer Clarence Wormley's daughter Maralyn stands a Chicago city flag after her mother, Sharon, received it from the mayor Saturday.

A LEGACY: 'BE KIND'

Teenage daughter of fallen police officer brings mourners to their feet

By Jeremy Gorner and Annie Sweeney
Chicago Tribune

She reached for a hero and a light in the city of Chicago but the most touching tribute during Saturday's funeral for fallen police Officer Clarence Wormley came from his oldest daughter.

"Hi, Dad. I miss you so much," Rebecca Wormley said through tears at St. Rita of Cascia Shrine Chapel, where a day earlier attendees were told to honor Wormley's partner, Officer Conrad Cary. The two were struck and killed by a crash as they pursued a suspect Monday in an area near Irving Park Road and Dayton Avenue on the far North Side.

"I love as much as my dad

Rebecca Wormley

now there's no time," Rebecca, 18, said. "But as long as every one you again breaks my heart into a million pieces, you always had faith in me, and that kept me going.

"Now that you've checked out, it's my turn to carry the child," she continued, struggling to keep from crying.

"He taught me the smallest

Turn to Tribute, Page 8

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 12/17/2018 2:07:21 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: [KTBS 3] Toxic pollution from Sterigenics protests

And Louisiana!

https://www.ktbs.com/news/health/toxic-pollution-from-sterigenics-protests/article_6058664c-0158-11e9-a4cf-0778bd93ecd9.html?utm_medium=social&utm_source=email&utm_campaign=user-share

Sent from my iPhone

Message

From: Jennifer McConahy **Personal Email / Ex. 6**
Sent: 12/12/2018 1:23:53 AM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: A few questions

Hi Laura,

I aim taking you up on your offer to answer some questions that I have since we ran out of time at the community forum. If you are not able to answer these questions, can you direct me to someone who might? Thank you in advance for your responses.

1. Does the EPA oversee the IEPA? How does this oversight apply to operating permits issues by the state that fail to meet conditions of operating permits?

2. When Micro-Biotrol (former Sterigenics) was emitting over 100 tons of EtO into the air from 1985-1986 where was the EPA? This was allowable?

3. Where was the EPA when the IEPA knowingly allowed Griffith Micro (former Sterigenics) to dump large amounts of ethylene glycol into the waste treatment center. Yes, I have documents to verify.

4. Where was the EPA when Griffith was dumping ethylene glycol into the sewers while IEPA knew and renewed their permit?

I will likely have more questions, but hoping to get some answers to these. Clearly this company is a terrible neighbor and has been polluting out communities for decades.

Thanks-
Jen

Message

From: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Sent: 12/7/2018 5:58:06 PM
To: laura@kamedulski.com; Personal Email / Ex. 6; Personal Email / Ex. 6; Personal Email / Ex. 6; Jmerrinefte@IllinoisRealtors.org; Personal Email / Ex. 6; karendyterroson@omeritech.net; Personal Email / Ex. 6; Personal Privacy / Ex. 6; Personal Privacy / Ex. 6; Morgan, James [James.Morgan@illinois.gov]; thinshaw@indianheadpark-il.gov; drottenberg@atg.state.il.us; john.j.kim@illinois.gov; Personal Privacy / Ex. 6; Personal Privacy / Ex. 6; Personal Privacy / Ex. 6; mark.thomas@dgtownship.com; Personal Privacy / Ex. 6
CC: Wilson, Holly [Wilson.Holly@epa.gov]
Subject: First round of monitoring data

Hi folks,

Thanks for signing up for the notifications on information for the communities in around Sterigenics. The initial data from U.S. EPA's air quality monitoring are posted. Information about the results, including a link to the interactive map and a link to FAQs about the results, is available at this link: https://www.epa.gov/il/sterigenics-willowbrook-facility-latest-update

We will be holding a webinar in the next couple of weeks to discuss the monitoring data. We will be sending the information about that webinar soon. Please feel free to contact me if you have questions.

Thanks
Laura McKelvey, Group Leader
Community and Tribal Programs Group
Office of Air Quality Planning and Standards
919-541-5497

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 1/25/2019 10:10:18 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Tribune article

https://www.chicagotribune.com/news/local/breaking/ct-met-sterigenics-medline-vantage-epa-letter-20190125-story.html

Sent from my iPhone

Message

From: Jennifer McConahy [redacted] **Personal Email / Ex. 6**
Sent: 1/15/2019 2:18:08 AM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Willowbrook letter
Attachments: 2019-01-10 Letter from Willowbrook to IEPA.pdf

Hi Laura-
We are sure hoping the EPA is back running again soon. What a mess. Just getting back to passing along some documents to you. Both Burr Ridge and Willowbrook May continue with more private air testing..... we had a very successful fundraiser this past weekend. Citizens for Clean Air was started at a new political action group...:we are gaining more national attention. We hope the new governor and ILEPA director take some action.
Jen

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 12/10/2018 2:37:16 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Help!
Attachments: IMG-2105.JPG

Good morning-
I just wanted to share the post that came out Friday afternoon from our local elementary and middle school districts. They have immediately started rerouting the school busses away from Sterigenics as a result of Fridays test results. How does the EPA explain how are children are to live this way? I plan on sharing this with other officials with the EPA, but seeing as I never got a call back from Bill W, or Mike K, and Wheelers mailbox is full I am not expecting much.

Please advise on what other measures we can take to ensure we are safe. Because we are not.
Jen

GOWER DISTRICT NEWS

UPDATED COMMUNITY NOTICE: Sterigenics Inc. and Ethylene Oxide

December 7, 2018 – – EPA posts initial 3 days of ambient monitoring around Sterigenics Willowbrook facility

The U.S. EPA has posted results for three days of air quality monitoring around the Sterigenics Willowbrook (November 13, 16 and 19, 2018). Information about the results, including a link to the interactive map and a link to FAQs about the results, is available at this link: https://www.epa.gov/il/sterigenics-willowbrook-facility-latest-update. It is important to recognize that the EPA is expected to continue to post updates related to the issue at this website directly. Gower School District Officials will continue to provide updates as they are made available and encourage members of our community to visit the EPA website for the most direct and updated information. In summary:

- EPA Monitors detected ethylene oxide in the air at the two sites closest to the Sterigenics facility.
- EPA Monitors did not detect ethylene oxide at the six community-oriented sites — including those at schools and in residential areas.
- EPA plans to continue monitoring in the Willowbrook area for three months and will continue to post data as it becomes available.
- EPA will conduct a full assessment of risk from ethylene oxide in Willowbrook, which is expected to be completed by Spring 2019.
- Although it may be premature to draw conclusions related to the most recent data posted by the EPA, District Officials will re-route buses, using Willowbrook Center Parkway exclusively, to bypass the area at which ethylene oxide has been detected effective immediately. As the current information does not support a claim of an immediate health risk, this decision is being made out of an abundance of caution as the EPA continues its monitoring of the area and can carry out a full risk assessment.

November 20, 2018 – – For Public Notice and Board Correspondence – – Use this link to view/download correspondence directly

TO: Board of Education, Gower School District 62; All Certified and Non-Certified Staff
FROM: Dr. Victor Simon, Superintendent of Schools, vsimon@gower62.com
RE: Sterigenics-Ethylene Oxide Issue – For Public Notice and Board Correspondence
DATE: Nov. 20, 2018

Background: The Gower 62 website can be found at www.gower62.com and is used as a valuable source of information related to our school community. In addition to this form of communication, Gower utilizes mass-email and robo-call lists for contacts in our student information system. The annual registration process allows parents and legal guardians to opt in to our direct email outreach and communication efforts. More information regarding our communication strategy can be found in the Parent/Student Handbook (pp. 9-10).

Message

From: Kristi Celico Personal Privacy / Ex. 6
Sent: 11/28/2018 10:32:23 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]; Wilson, Holly [Wilson.Holly@epa.gov]; doug@forumfg.com; Debra Duerr Personal Email / Ex. 6 Alec.Messina@illinois.gov; Donnell Margaret [Margaret.Donnell@hiscox.com]; thinshaw@indianheadpark-il.gov
Subject: EPA Forum: Information for Session 3
Attachments: Streamlined Questions by Session 11 28 18.xlsx; Raw binned Questions as of 11 28 18.xlsx

Dear Panel members and questioners for Session Three:

Thanks for agreeing to participate in session three. Below is a summary of your agenda section:

9:00 PM Panel Session 3. Community questions related to future plans to inform and engage the community surrounding the Sterigenics Willowbrook facility

Community Questioners: Mayor Tom Hinshaw, Village of Indian Head Park & Margaret Donnell, Stop Sterigenics Group

Panelists:

- US EPA – Laura McKelvey, Leader, Community and Tribal Programs Group, Office of Air Quality Planning and Standards (OAQPS)
- Illinois EPA – Alec Messina, Director

EPA will be sending an updated agenda soon.

Attached please find two documents:

- The list of raw questions that came in from the public. Two things: Some community members submitted over 60 pages of questions. EPA summarized these. Also, some additional questions came in after the Monday night deadline. Congressman Lipinski encouraged folks to send in questions in a recent mailing but did not note the cut-off date. We will try to deal with these as best as possible by including them in the Q and A session. Please note this document is an Excel sheet and it has two pages to it.
- An organized and streamlined version of the questions to help focus the panel interaction. Please note this is an Excel Sheet. Go to Session three of this document. EPA reviewed all the questions and tried to identify ones that:
    - Are of greatest concern to the community (e.g., many people asked it);
    - Are best for a public forum (e.g., not questions about the details of a particular individual's health problem—but instead those that address community health concerns).
    - Help share most of the key information in an order that makes some logical sense.

Tom and Margie will be asking the questions. The questioners can ask follow-up questions if they do not understand the answer or feel that the response does not answer the question. The challenge will be there is only 1/2 hour for this session--so it is your job to thoughtfully get through as many questions as possible within the limited time. (Please know that EPA has agreed to answer most all the questions they received in writing too. These will be posted on their website at a later time.)

A couple of tasks:

- If your name or title above is wrong, please contact Holly immediately. Her email is Wilson.holly@epa.gov
- Please review the questions in the second attachment for completeness and flow. If you have suggestions for change, please send them back to everyone on this email so that we can try to get quick resolution. Given the tightness of the schedule, please include your recommended change--do not just state a concern. Please send any suggestions by no later than noon on Thursday.

We fully appreciate this is a challenging task and a tight schedule. We are very grateful for all of you for working under these difficult conditions.

Doug Sarno and Kristi Celico

Meeting Facilitators -- --
Kristi Parker Celico
Public Policy Mediator/Facilitator

Personal Privacy / Ex. 6

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 2/26/2019 7:50:24 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Sterigenics closed until at least 4/9

They won't have a hearing until then, at the earliest. Another huge victory as we push them out.

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 12/19/2018 2:36:40 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: PDF's of documents
Attachments: 12-19 Press Release.pdf; 12-19-18 Reaction to 1984 Document.pdf; 1984-07-06-letter-from-IEPA-1.pdf; second_data_set_foot USEPA.pdf

HI Laura-
Here are the PDF's to the link I sent earlier. Could you send me Josh Lewis email as well?
Jen

Message

From: Jennifer McConahy **Personal Email / Ex. 6**
Sent: 2/19/2019 2:39:57 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Headed to Illinois capital today

A bus full of stop sterigenics people headed to Springfield to talk with legislators about banning EtO emissions in Illinois! No offense but we are going to get this done without the Help of the EPA!

and well being of our communities!

Message

From: Jennifer McConahy [redacted] **Personal Email / Ex. 6**
Sent: 2/18/2019 1:17:30 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: The Sterigenics clampdown: As U.S. EPA fiddles, Illinois EPA acts - Chicago Tribune

The Sterigenics clampdown: As U.S. EPA fiddles, Illinois EPA acts - Chicago Tribune

https://www.chicagotribune.com/news/opinion/editorials/ct-edit-sterigenics-epa-illinois-pritzker-20190217-story.html

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 2/15/2019 11:29:28 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Rumor?

I know it's the weekend....but there are rumors flying that a sterigenics is getting shut down this evening! I'm saying my prayers! Will keep you posted!

Message

From: Jennifer McConahy **Personal Email / Ex. 6**
Sent: 2/14/2019 10:37:23 AM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Time's up, EPA. Solve the Sterigenics problem. - Chicago Tribune

Time's up, EPA. Solve the Sterigenics problem. - Chicago Tribune

https://www.chicagotribune.com/news/opinion/editorials/ct-edit-sterigenics-epa-air-pollution-cancer-20190214-story.html

Message

From: Jennifer McConahy Personal Email / Ex. 6
Sent: 12/12/2018 5:32:49 PM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: Projected Cumulative Cancer Risk Rates Document
Attachments: Cancer rate based on concentration misc values rev 1.xlsx

Hi Laura,

I am sending you a document that multiple private citizens have worked on over the course of multiple weeks. We are asking for accuracy of the risk calculations that were determined. Can you provide any feedback or send to others on your team that would have this expertise?
Thanks,
Jen

Message

From: Jennifer McConahy **Personal Email / Ex. 6**
Sent: 5/21/2019 1:22:32 AM
To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: ?

Hi-
Sterigenics is considered a "major source." Correct? Wouldn't this make them eligible for a continuous monitoring system?
And how are two facilities operating under one permit?
Thanks
Jen

Message

From: Mckelvey, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F3A2C5F041A442EA931DDB3D039236FF-LMCKELVE]
Sent: 3/7/2019 7:20:34 PM
To: laura@kamedulski.com; Personal Email / Ex. 6; Personal Email / Ex. 6; Personal Email / Ex. 6; merrinette@IllinoisRealtors.org; Personal Email / Ex. 6; Personal Email / Ex. 6; Personal Email / Ex. 6; Personal Privacy / Ex. 6; mark.thoman@DGTownship.com; Personal Email / Ex. 6; john.j.kim@illinois.gov; James.Morgan@illinois.gov; drottenberg@atg.state.il.us; thinshaw@indianheadpark-il.gov; ssylvester@atg.state.il.us; Personal Email / Ex. 6; Margaret.Donnell@HISCOX.com; THalik@Willowbrook.il.us; Kgargano@villageofhinsdale.org; sbucha3@uic.edu; Kim.biggs@illinois.gov; smcivor@darienil.gov; jdurcher@indianheadpark-IL.gov; Personal Email / Ex. 6; Personal Email / Ex. 6; ehabercoss@tristatefed.com; Personal Email / Ex. 6; blaw@hinsdale86.org; vsimon@gower62.com; Ewalter@burr-ridge.gov; kweaver@darienil.gov; Bcana@darienil.gov; Ivaughan@darienil.gov; Personal Email / Ex. 6; tom.cuculich@dupageco.org; Chairman@dupageco.org; Laura.Roche@Illinois.gov; Brad.Frost@illinois.gov; Julie.Armitage@Illinois.gov; Kathy_Weaver@AJG.com; laura@kamedulski.com; Personal Email / Ex. 6; Personal Email / Ex. 6; Jmerrinette@IllinoisRealtors.org; Personal Email / Ex. 6; Personal Email / Ex. 6; Personal Email / Ex. 6; john.j.kim@illinois.gov; James.Morgan@illinois.gov; drottenberg@atg.state.il.us; thinshaw@indianheadpark-il.gov; ssylvester@atg.state.il.us; Personal Email / Ex. 6; echeuse@earthjustice.org; Personal Email / Ex. 6; Margaret.Donnell@HISCOX.com; THalik@Willowbrook.il.us; Kgargano@villageofhinsdale.org; sbucha3@uic.edu; Kim.biggs@illinois.gov; smcivor@darienil.gov; jdurcher@indianheadpark-IL.gov; Personal Email / Ex. 6; ehabercoss@tristatefed.com; Personal Email / Ex. 6; blaw@hinsdale86.org; vsimon@gower62.com; Ewalter@burr-ridge.gov; kweaver@darienil.gov; Bcana@darienil.gov; Ivaughan@darienil.gov; Personal Email / Ex. 6; tom.cuculich@dupageco.org; Chairman@dupageco.org; Laura.Roche@Illinois.gov; Brad.Frost@illinois.gov; Julie.Armitage@Illinois.gov; Kathy_Weaver@AJG.com; MDUNN@atg.state.il.us; mickey@samusa.com; quino@quino.com; echeuse@earthjustic.org; Curtis.Michols@abbott.com
Subject: Willowbrook EtO data for January 22 to February 11 is now on the web

Hi folks

Heads up the Data through 2/11 is now posted at: https://www.epa.gov/il/outdoor-air-monitoring-data-willowbrook-community

Please call in to the webinar this afternoon

Webinar:
Date: Thursday, March 7, 2019
Time: 3:00 to 4:00 p.m. (CT)
Meeting Link: https://epawebconferencing.acms.com/willowbrook

Phone line is Conf. Code/Line/Ex. 6

Access code is: Conf. Code/Line/Ex. 6

*Note: If you are at a computer, please listen through your computer speakers. We have a capacity of 500 people via computer. If you're not able to be at a computer, you'll be able to listen to the Webinar by phone. The phone line has a capacity of 125.

Materials will be posted on the website after the webinar at https://www.epa.gov/il/sterigenics-willowbrook-facility

If you have never attended an Adobe Connect meeting before, test your connection by visiting http://admin.adobeconnect.com/common/help/en/support/meeting_test.htm. *You may also get a quick overview by visiting* http://www.adobe.com/products/adobeconnect.html.

1. Click "Enter as a Guest"
2. Type in your first & last name and organization
3. Click "Enter Room"
4. You will be in the room!

Message

From: Mckelvey, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F3A2C5F041A442EA931DDB3D039236FF-LMCKELVE]
Sent: 11/15/2018 6:22:23 PM
To: nirav.shah@illinois.gov
Subject: Willowbrook Community meeting on Ethylene Oxide issues

Hellow Dr. Shah,

My name is Laura McKelvey, and I work for the US Environmental Protection Agency (EPA) I am leading an EPA effort to engage the communities living around Sterigenics, a commercial facility that sterilizes medical equipment using ethylene oxide (EtO) . As I'm sure you are aware, emissions of EtO from the facility have raised concerns throughout Willowbrook and nearby communities. We have been working with the elected officials and community members to develop the agenda for the meeting. The goal is to provide information to community questions regarding EtO, what is known and not known about the specific conditions and risks at the Willowbrook Sterignics facility; provide an understating of the various government agencies activities and plans to move forward, and Identify a path forward for community information and engagement. I know this is late notice but I would like to invite you or someone from your staff to participate in the meeting and the open house preceding the meeting to discuss your cancer study, and health information that might be helpful for this community.

I can be reached via this email address or at Personal Privacy / Ex. 6 Thank you for your help in this matter.

Laura McKelvey, Group Leader

US EPA
Office of Air Quality Planning and Standards
Community and Tribal Programs Group

Message

From: Mckelvey, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F3A2C5F041A442EA931DDB3D039236FF-LMCKELVE]
Sent: 4/23/2019 6:56:28 PM
To: slibicki@ramboll.com
Subject: EPA webinars

EPA Webinars

The U.S. Environmental Protection Agency (EPA) will hold two webinars this week. The first webinar, *Techniques and Skills for Providing Effective Input in the EPA Rulemaking Process,* will be at 4 p.m. Central Daylight Time, Wednesday, April 24, 2019. The second webinar, covering monitoring data from March 2019, will be at 4 p.m. CDT on Friday, April 26, 2019. Information on these webinars is below:

Webinar:
Date: Wednesday, April 24, 2019
Time: 4:00 to 5:00 (CDT)
Meeting Link: https://epawebconferencing.acms.com/willowbrook

Phone line
Access code Conference Line and Code / Ex. 6

Webinar:
Date: Friday, April 26, 2019
Time: 4:00 to 5:00 (CDT)
Meeting Link: https://epawebconferencing.acms.com/willowbrook

Phone line
Access code Conference Line and Code / Ex. 6

*Note: If you are participating via a computer, please listen through your computer speakers. We have a capacity of 500 people via computer. If you're not able to be at a computer, you'll be able to listen to the Webinar by phone. The phone line has a capacity of 125.

Materials will be posted after the webinar at https://www.epa.gov/il/sterigenics-willowbrook-facility

If you have never attended an Adobe Connect meeting before, test your connection by visiting http://admin.adobeconnect.com/common/help/en/support/meeting_test.htm*. You may also get a quick overview by visiting* http://www.adobe.com/products/adobeconnect.html.

1. Click "Enter as a Guest"
2. Type in your first & last name and organization
3. Click "Enter Room"
4. You will be in the webinar!

Message

From: Jablonowski, Eugene [jablonowski.eugene@epa.gov]
Sent: 3/1/2019 8:29:02 PM
To: Mitchell, James [mitchell.james@epa.gov]
Subject: Willowbrook Documents
Attachments: California 2015guidancemanual.pdf; NIOSH Chemical Carcinogen Policy 2017-100.pdf; Willowbrook Village 11183332-Village of Willowbrook EtO Air Monitoring Report.pdf; Willowbrook Village Air Monitoring Q&A (11.19.18).docx.pdf; Willowbrook Village EtO Followup Testing Results Release 02-15-19 Final plus results.pdf; ATSDR Sterigenics_International_Inc-508.pdf; PEHSU_GrandRounds_Jan_16_2019_EthyleneOxide_Slides.pdf

After recent discussions, I looked up the ethylene oxide exposure limits and figured I'd put together a table to summarize them in ppm, ppb, mg/m3, and ug/m3.

- 1 ppm = 1.80 mg/m3
- 1 ppb = 1.80 ug/m3
- Ethylene oxide exposure limits from CDC/NIOSH: https://www.cdc.gov/niosh/npg/npgd0275.html
- Cal-EPA Chronic REL (reference for the "0.02" that was discussed): https://oehha.ca.gov/chemicals/ethylene-oxide
- ATSDR CREGS from their health consultation (attached)

Exposure Limit	Concentration (ppm)	Concentration (ppb)	Concentration (mg/m3)	Concentration (ug/m3)
ATSDR's CREG for EtO at 10-6 risk	0.00000	0.00012	0.00000	0.00021
ATSDR's CREG for EtO at 10-5 risk	0.00000	0.00117	0.00000	0.00210
ATSDR's CREG for EtO at 10-4 risk	0.00001	0.01167	0.00002	0.02100
California EPA Chronic Inhalation REL	0.01667	16.66667	0.03000	30.00000
NIOSH REL Ca TWA	0.10000	100.00000	0.18000	180.00000
NIOSH REL C	5.00000	5000.00000	9.00000	9000.00000

NIOSH "RELs" are explained in the Exposure Limits section of this web page:
https://www.cdc.gov/niosh/npg/pgintrod.html

- For NIOSH RELs, "**TWA**" indicates a time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek.
- Any substance that NIOSH considers to be a potential occupational carcinogen is designated by the notation " **Ca** "

The NIOSH Chemical Carcinogen Policy discusses excess risk levels of the RELs and new RMLs (attached)...

- NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000, exposed to the substance for a 45-year working life-time.

The California EPA Chronic Inhalation REL for ethylene oxide is here: https://oehha.ca.gov/chemicals/ethylene-oxide

- The explanation of the California EPA Chronic REL is in section 6.4 of the attached Cal EPA Risk Assessment Guidelines document: *"A chronic REL is a concentration level (expressed in units of micrograms per cubic meter (μg/m3) for inhalation exposure and in a dose expressed in units of milligrams per kilogram-day (mg/kg-day) for oral exposures) at or below which no adverse health effects are anticipated following long-term exposure. Long-term exposure for these purposes has been defined by U.S. EPA as at least 12% of a lifetime, or about eight years for humans."*

Here's an EPA hazard summary I located for ethylene oxide via Google with a nice table of toxity, health, and risk values vs concentration, and more conversion factors: https://www.epa.gov/sites/production/files/2016-09/documents/ethylene-oxide.pdf

I also attached the three Village of Willowbrook monitoring documents I found.

I also attached recent PowerPoint/PDF from a local environmental pediatrics group (PEHSU).

--

Eugene A. Jablonowski Jr., M.S., Health Physicist
U.S. EPA Region 5 Superfund Division
77 W. Jackson Blvd (SMF-5J)
Chicago, IL 60604
(312) 886-4591 office
jablonowski.eugene@epa.gov

Message

From: Mitchell, James [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D6A029B71AAA46F79895AE39FB5052CC-JMITCH05]
Sent: 3/6/2019 10:31:00 PM
To: Jacob Hassan [Hassan.Jacob@epa.gov]
Subject: FW: Sterigenics Webinar (Found this on Twitter)

FYI

From: Dave Rebot Personal Email / Ex. 6
Sent: Wednesday, March 06, 2019 4:28 PM
To: Cooper, Brian <cooper.brian@epa.gov>; Canar, John <canar.john@epa.gov>; Roth, Charles <roth.charles@epa.gov>; Rebot, David <rebot.david@epa.gov>; Ursic, James <ursic.james@epa.gov>; Ruesch, Paul <ruesch.paul@epa.gov>; Matt Blaser Personal Email / Ex. 6 Mitchell, James <mitchell.james@epa.gov>; Padovani, Steven <padovani.steven@epa.gov>
Subject: Sterigenics Webinar (Found this on Twitter)

EPA WEBINAR TOMORROW 3/7/19 at 3p CT
EPA's Ethylene Oxide Monitoring data for #Sterigenics, covering January 22, 2019 to February 11, 2019.
Website:
https://epawebconferencing.acms.com/willowbrook

Conf. Line/Code/Ex. 6

Appointment

From: Shappley, Ned [Shappley.Ned@epa.gov]
Sent: 9/4/2018 2:27:32 PM
To: Shappley, Ned [Shappley.Ned@epa.gov]; Mattison, Kevin [Kevin.Mattison@Illinois.gov]; Witt, Jon [Witt.Jon@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]; Sieffert, Margaret [Sieffert.Margaret@epa.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]; conf. Line/Ex. 6 Phone-Line/RTP-OAQPS-BLDG-C [RTP-OAQPS-conf. Line/Ex. 6 Segall, Robin [Segall.Robin@epa.gov]; Merrill, Raymond [Merrill.Raymond@epa.gov]
CC: Thurman, James [Thurman.James@epa.gov]; Nguyen, Phuong [Nguyen.Phuong@epa.gov]

Subject: FW: Sterigenics - Willowbrook
Location: RTP-OAQPS-E141B/RTP-OAQPS-BLDG-E

Start: 9/4/2018 6:30:00 PM
End: 9/4/2018 7:30:00 PM
Show Time As: Tentative

Appointment

From: Cain, Alexis [cain.alexis@epa.gov]
Sent: 6/21/2018 6:27:12 PM
To: Cain, Alexis [cain.alexis@epa.gov]; Sieffert, Margaret [Sieffert.Margaret@epa.gov]; Damico, Genevieve [damico.genevieve@epa.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]
CC: Isom, Kristen [isom.kristen@epa.gov]; Nguyen, Phuong [Nguyen.Phuong@epa.gov]; Olson, Erik [olson.erik@epa.gov]

Subject: FW: Sterigenics Permit
Location: Katie's Office

Start: 6/21/2018 7:00:00 PM
End: 6/21/2018 7:30:00 PM
Show Time As: Tentative

Appointment

From: Thurman, James [Thurman.James@epa.gov]
Sent: 9/5/2018 12:45:45 PM
To: Thurman, James [Thurman.James@epa.gov]; Nguyen, Phuong [Nguyen.Phuong@epa.gov]

Subject: Sterigenics modeling
Location: James will call Phuong

Start: 9/5/2018 7:00:00 PM
End: 9/5/2018 7:30:00 PM
Show Time As: Busy

Appointment

From: Thurman, James [Thurman.James@epa.gov]
Sent: 9/5/2018 3:32:05 PM
To: Nguyen, Phuong [Nguyen.Phuong@epa.gov]

Subject: Sterigenics modeling
Location: James will call Phuong

Start: 9/5/2018 7:00:00 PM
End: 9/5/2018 7:30:00 PM
Show Time As: Tentative

Appointment

From: Siegel, Kathryn [siegel.kathryn@epa.gov]
Sent: 6/21/2018 6:27:11 PM
To: Nguyen, Phuong [Nguyen.Phuong@epa.gov]

Subject: FW: Sterigenics Permit
Location: Katie's Office

Start: 6/21/2018 7:00:00 PM
End: 6/21/2018 7:30:00 PM
Show Time As: Tentative

Appointment

From: Nguyen, Phuong [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F07188263D014E06A28762CCF129CE20-PNGUYEN]
Sent: 5/9/2019 1:13:28 PM
To: Colledge, Michelle (ATSDR/DCHI/CB) [mna9@cdc.gov]

Subject: Accepted: FW: Sterigenics Assessment Update for R5 Staff
Location: ATSDR office: Room **Conf. Code/Code/Ex. 6**

Start: 5/9/2019 1:30:00 PM
End: 5/9/2019 3:00:00 PM
Show Time As: Busy

Appointment

From: Glass, Geoffrey [GLASS.GEOFFREY@EPA.GOV]
Sent: 9/12/2018 10:37:04 PM
To: Glass, Geoffrey [GLASS.GEOFFREY@EPA.GOV]; Ball, Harold [Ball.Harold@epa.gov]; Ballew, Mary [ballew.mary@epa.gov]; Batka, Sheila [Batka.Sheila@epa.gov]; Bellizzi, Carol [Bellizzi.Carol@epa.gov]; Benner, Tim [Benner.Tim@epa.gov]; Bollweg, George [bollweg.george@epa.gov]; Boyes, William [Boyes.William@epa.gov]; Brown, Catherine [Brown.Catherine@epa.gov]; Burton, Laureen [Burton.Laureen@epa.gov]; Bussard, David [Bussard.David@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]; Casso, Ruben [Casso.Ruben@epa.gov]; Chow, Alice [chow.alice@epa.gov]; Cook, Rich [Cook.Rich@epa.gov]; Costa, Dan [Costa.Dan@epa.gov]; D'Amico, Louis [DAmico.Louis@epa.gov]; Danois, Gracy R. [Danois.Gracy@epa.gov]; Davidson, Ken [Davidson.Ken@epa.gov]; Davis, Christine [Davis.Christine@epa.gov]; Doolan, Stephanie [Doolan.Stephanie@epa.gov]; Durkee, Stanley [Durkee.Stan@epa.gov]; Dye, Janice [Dye.Janice@epa.gov]; Fann, Neal [Fann.Neal@epa.gov]; Ferreira, Gina [Ferreira.Gina@epa.gov]; French, Chuck [French.Chuck@epa.gov]; Fry, Jessica [fry.jessica@epa.gov]; Fuoco, Marta [fuoco.marta@epa.gov]; Goehl, Eric [Goehl.Eric@epa.gov]; Goold, Megan [Goold.Megan@epa.gov]; Graham, Stephen [Graham.Stephen@epa.gov]; Gross-Davis, CarolAnn [Gross-Davis.CarolAnn@epa.gov]; Hansen, Linnea [Hansen.Linnea@epa.gov]; Hassett-Sipple, Beth [Hassett-Sipple.Beth@epa.gov]; Helmer, Kent [Helmer.Kent@epa.gov]; Helmich, Richard [Helmich.Richard@epa.gov]; Hemby, James [Hemby.James@epa.gov]; Hetes, Bob [Hetes.Bob@epa.gov]; Hiatt, Gerald (Separated 6/25/18) [Hiatt.Gerald@epa.gov]; Hirtz, James [Hirtz.James@epa.gov]; Hoang, Kim [Hoang.Kim@epa.gov]; Hogan, Sean [Hogan.Sean@epa.gov]; Hotchkiss, Andrew [Hotchkiss.Andrew@epa.gov]; Hoyer, Marion [hoyer.marion@epa.gov]; Jackson, Scott [Jackson.Scott@epa.gov]; Jarabek, Annie [Jarabek.Annie@epa.gov]; Jenkins, Scott [Jenkins.Scott@epa.gov]; Johnson, Jeremy [Johnson.Jeremy@epa.gov]; Johnson, Karen T. [Johnson.Karent@epa.gov]; Jones, Samantha [Jones.Samantha@epa.gov]; Kaleri, Cynthia [kaleri.cynthia@epa.gov]; Keteles, Kristen [Keteles.Kristen@epa.gov]; Kierys, Dawid [kierys.dawid@epa.gov]; King, Suzanne [king.suzanne@epa.gov]; Koporec, Kevin [Koporec.Kevin@epa.gov]; Kopylev, Leonid [Kopylev.Leonid@epa.gov]; Kramer, Elizabeth [Kramer.Elizabeth@epa.gov]; Kryak, DavidD [Kryak.Davidd@epa.gov]; Lancey, Susan [lancey.susan@epa.gov]; Langstaff, John [Langstaff.John@epa.gov]; Lau, Gavin [Lau.Gavin@epa.gov]; Lorang, Phil [Lorang.Phil@epa.gov]; Louis, Egide [Louis.Egide@epa.gov]; Maddaloni, Mark [Maddaloni.Mark@epa.gov]; Madden, Joshua [madden.joshua@epa.gov]; Mannshardt, Elizabeth [Mannshardt.Elizabeth@epa.gov]; Marrero, Jeanette [Marrero.Jeanette@epa.gov]; Mazur, Sarah [Mazur.Sarah@epa.gov]; McCoy, Britney [McCoy.Britney@epa.gov]; McDonnell, Ida [McDonnell.Ida@epa.gov]; Mehta-Sampath, Ameesha [Mehta-Sampath.Ameesha@epa.gov]; Merrill, Raymond [Merrill.Raymond@epa.gov]; Meyer, Cynthia [Meyer.Cynthia@epa.gov]; Miller, Latoya [Miller.Latoya@epa.gov]; Miller, Linda [miller.linda@epa.gov]; Mitchell, Ken [Mitchell.Ken@epa.gov]; Morozov, Viktor [Morozov.Viktor@epa.gov]; Moses, Althea [Moses.Althea@epa.gov]; Murphy, Deirdre [Murphy.Deirdre@epa.gov]; Murphy, Stacy [Murphy.Stacy@epa.gov]; Narvaez, Madonna [Narvaez.Madonna@epa.gov]; Neas, Lucas [Neas.Lucas@epa.gov]; Newman, Erin [newman.erin@epa.gov]; Nguyen, Phuong [Nguyen.Phuong@epa.gov]; Nwia, Jacqueline [nwia.jacqueline@epa.gov]; Olson, Kyle [Olson.Kyle@epa.gov]; Page, Lee [Page.Lee@epa.gov]; Palma, Ted [Palma.Ted@epa.gov]; Parker, Cindy [parker.cindy@epa.gov]; Parsons, Christy [Parsons.Christy@epa.gov]; Phelps, Lara [Phelps.Lara@epa.gov]; Pollard, Solomon [Pollard.Solomon@epa.gov]; Rennie, Gary [Rennie.Gary@epa.gov]; Richmond-Bryant, Jennifer [Richmond-Bryant.Jennifer@epa.gov]; Riddell, Dorothy [Riddell.Dorothy@epa.gov]; Riley, Alison [riley.alison@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Rivas, Marcus [Rivas.Marcus@epa.gov]; Robinson, Randall [robinson.randall@epa.gov]; Rogan, John [Rogan.John@epa.gov]; Russo, Bill [Russo.Bill@epa.gov]; Sacks, Jason [Sacks.Jason@epa.gov]; Sams, Reeder [Sams.Reeder@epa.gov]; Sargeant, Kathryn [sargeant.kathryn@epa.gov]; Sarsony, Chris [Sarsony.Chris@epa.gov]; Schulingkamp, Cristina [schulingkamp.cristina@epa.gov]; Serda, Sophia [Serda.Sophia@epa.gov]; Shelow, David [Shelow.David@epa.gov]; Shrager, Brian [Shrager.Brian@epa.gov]; Sieffert, Margaret [Sieffert.Margaret@epa.gov]; Singletary, DeAndre [Singletary.DeAndre@epa.gov]; Smith, Darcie [Smith.Darcie@epa.gov]; Sprenger, Mark [Sprenger.Mark@epa.gov]; Stanek, Lindsay [Stanek.Lindsay@epa.gov]; Stewart, Kathleen [Stewart.Kathleen@epa.gov]; Stewart, Michael [Stewart.Michael@epa.gov]; Stone, William [stone.william@epa.gov]; Stout, Dan [stout.dan@epa.gov]; Stralka, Daniel [Stralka.Daniel@epa.gov]; Strum, Madeleine [Strum.Madeleine@epa.gov]; Thayer, Kris [thayer.kris@epa.gov]; Trine, Rae [trine.rae@epa.gov]; Vandenberg, John [Vandenberg.John@epa.gov]; Vasu, Amy [Vasu.Amy@epa.gov]; Verhalen, Frances [verhalen.frances@epa.gov]; Vette, Alan [Vette.Alan@epa.gov]; Vianu, Libby [Vianu.Libby@epa.gov]; Watkins, Tim [Watkins.Tim@epa.gov]; Wilson, Holly [Wilson.Holly@epa.gov]; Wilson, Patrick [Wilson.Patrick@epa.gov]; Woodall, George [Woodall.George@epa.gov]; Woody, Matthew [Woody.Matthew@epa.gov]; Wroble, Julie [Wroble.Julie@epa.gov]; Yurk, Jeffrey [yurk.jeffrey@epa.gov]; Shappley, Ned [Shappley.Ned@epa.gov]; Larson,

Darrin [Larson.Darrin@epa.gov]; Ahuja, Akriti [ahuja.akriti@epa.gov]; Caparoso, Jennifer [Caparoso.Jennifer@epa.gov]; Witt, Jon [Witt.Jon@epa.gov]

Subject: FY19 Air Toxics Risk Assessment (ATRA) Monthly Call
Attachments: Canceled: FY19 Air Toxics Risk Assessment (ATRA) Monthly Call; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: FY19 Air Toxics Risk Assessment (ATRA) Monthly Call; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment
Location: Conference Line: Conf. Code/Code/Ex. 6

Start: 10/11/2018 3:30:00 PM
End: 10/11/2018 5:00:00 PM
Show Time As: Tentative

Recurrence: Monthly
the second Thursday of every 1 month(s) from 8:30 AM to 10:00 AM

Appointment

From: Colledge, Michelle (ATSDR/DCHI/CB) [mna9@cdc.gov]
Sent: 5/2/2019 4:34:06 PM
To: Colledge, Michelle (ATSDR/DCHI/CB) [mna9@cdc.gov]; Nguyen, Phuong [Nguyen.Phuong@epa.gov]; mkj5@cdc.gov; Sieffert, Margaret [Sieffert.Margaret@epa.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]; Bollweg, George [bollweg.george@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]; Compher, Michael [compher.michael@epa.gov]

Subject: FW: Sterigenics Assessment Update for R5 Staff
Location: ATSDR office: [redacted] **Conf. Line/Code/Ex. 6**

Start: 5/9/2019 1:30:00 PM
End: 5/9/2019 3:00:00 PM
Show Time As: Busy

Appointment

From: Colledge, Michelle (ATSDR/DCHI/CB) [mna9@cdc.gov]
Sent: 5/2/2019 4:34:06 PM
To: Colledge, Michelle (ATSDR/DCHI/CB) [mna9@cdc.gov]; Nguyen, Phuong [Nguyen.Phuong@epa.gov]; mkj5@cdc.gov; Sieffert, Margaret [Sieffert.Margaret@epa.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]; Bollweg, George [bollweg.george@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]; Compher, Michael [compher.michael@epa.gov]

Subject: FW: Sterigenics Assessment Update for R5 Staff
Location: ATSDR office: R[redacted] **Conf. Line/Code/Ex. 6**
Start: 5/9/2019 1:30:00 PM
End: 5/9/2019 3:00:00 PM
Show Time As: Busy

-----Original Appointment-----
From: Colledge, Michelle (ATSDR/DCHI/CB) <mna9@cdc.gov>
Sent: Thursday, May 02, 2019 11:17 AM
To: Colledge, Michelle (ATSDR/DCHI/CB); mkj5@cdc.gov; Sieffert, Margaret; Siegel, Kathryn; Bollweg, George; Cain, Alexis; Compher, Michael
Subject: Sterigenics Assessment Update for R5 Staff
When: Thursday, May 09, 2019 8:30 AM-10:00 AM (UTC-06:00) Central Time (US & Canada).
Where: ATSDR office: Room [redacted] **Conf. Line/Code/Ex. 6**

Call to update R5 EPA on ATSDR's Sterigenics Assessment

Appointment

From: Nguyen, Phuong [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F07188263D014E06A28762CCF129CE20-PNGUYEN]
Sent: 5/9/2019 1:13:28 PM
To: Colledge, Michelle (ATSDR/DCHI/CB) [mna9@cdc.gov]

Subject: Accepted: FW: Sterigenics Assessment Update for R5 Staff
Location: ATSDR office: Room Conf. Line/Code/Ex. 6

Start: 5/9/2019 1:30:00 PM
End: 5/9/2019 3:00:00 PM
Show Time As: Busy

EPA Region 5 State Source Water Protection Managers Conference Call
Draft Meeting Notes

Participants:
IL: Rick Cobb and Anthony Dulka
IN: Jim Sullivan
MN: Steve Robertson
OH: Jeff Patzke
WI: Brian Austin
ORSANCO: Sam Dinkins
Region 5: Cary McElhinney and Wendy Drake

1. Deliberative Process / Ex. 5

2. Deliberative Process / Ex. 5

b.

c.

Deliberative Process / Ex. 5

d.

Deliberative Process / Ex. 5

3.

4.

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

6. **Next call**: Feb/March

Illinois EPA and IDPH / EPA Semi-Annual Call Agenda

Wednesday, November 14, 2018

9:00am-10:00am

Conference Line A Ex. 6 - Personal Privacy

Attendees in bold (invitees not attending are un-bolded)

IEPA: Dave McMillan, Rick Cobb, Jeri Long, Joanne Olson**, David Cook, Mary Reed**

IDPH: Eric Portz, Ken McCann, and Jamie Tosetti

EPA: Deb Baltazar (acting deputy WDD) for Linda Holst, **Tom Poy, Rita Bair,** Heather Shoven, **Janet Kuefler, Cynthia Meyer, Wendy Drake, Jennifer Crooks,** Andrea Porter, **Val Bosscher, La Yvette Collymore, Sahba Rouhani, Miguel Del Toral, Laura Cossa (from State and Tribal Programs Branch)**

Agenda – Discussion Topics

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

2. State

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Illinois EPA and IDPH / EPA Semi-Annual Call Agenda

Wednesday, November 14, 2018

9:00am-10:00am

Conference Line A Ex. 6 - Personal Privacy

Attendees

IEPA: Dave McMillan, Rick Cobb, Jeri Long, Joanne Olson**, David Cook, Mary Reed**

IDPH: Eric Portz, Ken McCann, and Jamie Tosetti

EPA: Deb Baltazar (acting deputy WDD) for Linda Holst, **Tom Poy, Rita Bair,** Heather Shoven, **Janet Kuefler, Cynthia Meyer, Wendy Drake, Jennifer Crooks,** Andrea Porter, **Val Bosscher, La Yvette Collymore, Sahba Rouhani, Miguel Del Toral, Laura Cossa (from State and Tribal Programs Branch)**

Agenda – Discussion Topics

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Message

From: Holst, Linda [holst.linda@epa.gov]
Sent: 2/4/2019 6:51:43 PM
To: Poy, Thomas [poy.thomas@epa.gov]
Subject: FW: EtO Water Sampling

Regarding Sterigenics related water sampling....

From: Nam, Ed
Sent: Friday, February 01, 2019 3:48 PM
To: Kelley, Jeff <kelley.jeff@epa.gov>; Holst, Linda <holst.linda@epa.gov>
Subject: FW: EtO Water Sampling

This came in during furlough. All clear on water. One of us should mention this on Monday's meeting.

http://www.chicagotribune.com/suburbs/burr-ridge/news/ct-dbr-sterigenics-water-testing-tl-0117-story.html

have a great weekend.
-Ed

Message

From: Hall, Todd [Todd.Hall@Illinois.gov]
Sent: 10/3/2018 3:33:37 PM
To: mkj5@cdc.gov
Subject: Sterigenics - Willowbrook - FOAI information

Hi Mark-

I just received your voicemail. All Site Remediation Program documents submitted to the Illinois EPA for the Sterigenics site can be accessed through our Document Explorer link which is found at:

https://external.epa.illinois.gov/DocumentExplorer/Attributes

Just enter the LPC# (0431105032) in the Bureau ID field. Available documents include the Site Investigation Report, which will discuss soil and groundwater sampling efforts conducted at the site.

If you have any questions let me know,

Thanks

Todd Hall
Illinois Environmental Protection Agency
Bureau of Land – Remedial Project Management Section
1021 North Grand Avenue East
P.O. Box 19276
Springfield, Illinois 62794-9276

(217) 557-1409
Todd.Hall@illinois.gov

Message

From: Poy, Thomas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D30804725BE4468B610F9863E2C938E-TPOY02]
Sent: 12/13/2018 4:30:58 PM
To: Holst, Linda [holst.linda@epa.gov]; Baltazar, Debbie [baltazar.debbie@epa.gov]
CC: Rita Bair - EPA [Bair.Rita@epa.gov]; Heather Shoven - EPA [Shoven.Heather@epa.gov]
Subject: FW: Willowbrook sampling
Attachments: Willowbrook Well Sampling News Release - Draft.docx; 2018_12_11 DCN242 QAPP010 for Ethylene Glycol and Ethylene Oxide Sampling.docx; FinalSamplingMap.pdf

Sample results from the lab on the private well sampling are expected at the end of Dec/early January.

Tom Poy
Chief, Ground Water and Drinking Water Branch
USEPA - Region 5
(312) 886-5991

From: Cobb, Rick <RICK.COBB@Illinois.gov>
Sent: Thursday, December 13, 2018 10:25 AM
To: Poy, Thomas <poy.thomas@epa.gov>; dave.mcmillan@illinois.gov
Subject: RE: Willowbrook sampling

Tom,

Yes, staff they are out today, and will UPS to the labs today. There is 7-8 day turn around. In addition, Aarom Martin will write the letter transmitting the results. Thus, it will in all likelihood be January.

Rick

From: Poy, Thomas <poy.thomas@epa.gov>
Sent: Thursday, December 13, 2018 9:38 AM
To: McMillan, Dave <DAVE.MCMILLAN@Illinois.gov>; Cobb, Rick <RICK.COBB@Illinois.gov>
Subject: [External] Willowbrook sampling

Dave/Rick: I heard that sampling of private wells was going to take place soon (this week?). When would you expect to get the results?

Tom

Tom Poy
Chief, Ground Water and Drinking Water Branch
USEPA - Region 5
(312) 886-5991

Message

From: Rountree, Jillian [Rountree.Jillian@epa.gov]
Sent: 2/20/2019 4:50:57 PM
To: Morgan, James [James.Morgan@illinois.gov]
CC: Rodman, Sonja [Rodman.Sonja@epa.gov]
Subject: EPA statement on Feb 7 meeting Sterigenics

Hi Jim,

Apologies this is coming in just now, but I wanted to let you know that this is what EPA plans to say if asked about the meeting among EPA, IEPA, IAG, and Sterigenics on February 7, 2019. Please let me know any questions. Thanks,

Deliberative Process / Ex. 5

Jillian Rountree
Air and Radiation Division Detail Attorney
U.S. EPA Region 5
77 W. Jackson Blvd. (C-14J), Cube 18010
Chicago, Illinois 60604
312-353-3849
rountree.jillian@epa.gov

Message

From: Cherepy, Andrea [Cherepy.Andrea@epa.gov]
Sent: 1/29/2019 8:48:27 PM
To: Rowson, David [Rowson.David@epa.gov]; Smith, Alisa [Smith.Alisa@epa.gov]; Veal, Lee [Veal.Lee@epa.gov]; White, Rick [White.Rick@epa.gov]; Griggs, John [Griggs.John@epa.gov]; Clark, Mike S. [Clark.Michael@epa.gov]; Wilds, Edward [Wilds.Edward@epa.gov]; Stafford, Andrea [Stafford.Andrea@epa.gov]
CC: Edwards, Jonathan [Edwards.Jonathan@epa.gov]; Bullard, Pamela [Bullard.Pamela@epa.gov]; Marbury, Candice [Marbury.Candice@epa.gov]
Subject: Final QFRs from the Administrator's hearing on January 16 & final factsheets from the nomination preparations
Attachments: 2019.01.28 - FINAL - ALL QFRs Wheeler 01.16.2019.pdf; OAR-16 CLEAN Radiation Protection Radiological Emergency Response.docx; OAR-13 CLEAN Wildfires.docx; OAR-6 CLEAN EtO in Illinois.docx

Good afternoon,

Attached are the final QFRs from the Administrator's hearing with the Senate EPW committee on January 16th. We've been asked to conduct a quick review of the document and flag any incorrect information. Unfortunately, OCIR only provided one large pdf document. I skimmed through the document and didn't see anything specific to our programs mentioned, so this email is really more of an FYI. (General emergency response language is peppered throughout the document; ethylene oxide is mentioned on page 51; lead testing in schools is mentioned on p. 66.) If you do happen to spot any incorrect information, please let me know by **COB Monday, February 4**. The Agency is expecting additional oversight requests from Congress and would like to be prepared with accurate information in advance of any requests that come in.

OCIR also just provided us with the final OAR Fact Sheets that made it into the Preparation's Book for the Acting Administrator's Nomination. Only a handful of the Fact Sheets that were drafted in the November/December timeframe made it into the final Prep Book. And only three of those relate to our programs; they are attached to this email as an FYI (no need for action).

Andrea

Andrea Cherepy | Chief of Staff | Office of Radiation & Indoor Air | U.S. Environmental Protection Agency | 202 343-9317 | cherepy.andrea@epa.gov

Appointment

From: Shappley, Ned [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5FC7FDE372054AB5AC38F24B9072B73D-SHAPPLEY, N]
Sent: 8/14/2018 5:29:15 PM
To: Shappley, Ned [Shappley.Ned@epa.gov]; Mattison, Kevin [Kevin.Mattison@Illinois.gov]; Witt, Jon [Witt.Jon@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]; Sieffert, Margaret [Sieffert.Margaret@epa.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]; RTP[Conf. Line/Code/Ex. 6]/Phone-Line/RTP-OAQPS-BLDG-C [RTP-OAQPS-[Conf. Line/Code/Ex. 6]epa.gov]; Robin Segall (Segall.Robin@epa.gov) [Segall.Robin@epa.gov]; Merrill, Raymond [Merrill.Raymond@epa.gov]
CC: Thurman, James [Thurman.James@epa.gov]; Nguyen, Phuong [Nguyen.Phuong@epa.gov]
BCC: RTP-OAQPS-E141B/RTP-OAQPS-BLDG-E [RTP-OAQPS-E141B@epa.gov]

Subject: Sterigenics - Willowbrook
Location: RTP-OAQPS-E141B/RTP-OAQPS-BLDG-E

Start: 9/4/2018 6:30:00 PM
End: 9/4/2018 7:30:00 PM
Show Time As: Busy

Appointment

From: Shappley, Ned [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5FC7FDE372054AB5AC38F24B9072B73D-SHAPPLEY, N]
Sent: 8/14/2018 5:29:18 PM
To: Mattison, Kevin [Kevin.Mattison@Illinois.gov]; Witt, Jon [Witt.Jon@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]; Sieffert, Margaret [Sieffert.Margaret@epa.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]; RT Conf. Line/Code/Ex. 6 Conf. Line/Code/Ex. 6 /RTP-OAQPS-BLDG-C [RTP-OAQPS Conf. Line/Code/Ex. 6 gov]; Robin Segall (Segall.Robin@epa.gov) [Segall.Robin@epa.gov]
BCC: RTP-OAQPS-E141B/RTP-OAQPS-BLDG-E [RTP-OAQPS-E141B@epa.gov]

Subject: Sterigenics - Willowbrook
Location: RTP-OAQPS-E141B/RTP-OAQPS-BLDG-E

Start: 9/4/2018 6:30:00 PM
End: 9/4/2018 7:30:00 PM
Show Time As: Tentative

Appointment

From: Shappley, Ned [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5FC7FDE372054AB5AC38F24B9072B73D-SHAPPLEY, N]
Sent: 8/30/2018 1:25:01 PM
To: Mattison, Kevin [Kevin.Mattison@Illinois.gov]; Witt, Jon [Witt.Jon@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]; Sieffert, Margaret [Sieffert.Margaret@epa.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]; RTP-OAQ[redacted]-Line/RTP-OAQPS-BLDG-C [RTP-OAQPS[redacted]epa.gov]; Robin Segan (Segan.Robin@epa.gov) [Segall.Robin@epa.gov]; Merrill, Raymond [Merrill.Raymond@epa.gov]
BCC: RTP-OAQPS-E141B/RTP-OAQPS-BLDG-E [RTP-OAQPS-E141B@epa.gov]

Subject: Sterigenics - Willowbrook
Location: RTP-OAQPS-E141B/RTP-OAQPS-BLDG-E

Start: 9/4/2018 6:30:00 PM
End: 9/4/2018 7:30:00 PM
Show Time As: Tentative

Message

From: Shappley, Ned [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5FC7FDE372054AB5AC38F24B9072B73D-SHAPPLEY, N]
Sent: 5/21/2019 2:40:29 PM
To: King, Steven [Steven.King@Illinois.gov]
Subject: Base Case

Steve,

Would you be able to speak about the base case you have used for Sterigenics on today's call?

Thanks,

Ned Shappley | USEPA|OAQPS|AQAD|Measurement Technology Group
109 TW Alexander Drive (E143-02) | Research Triangle Park, NC 27711
email: shappley.ned@epa.gov | Phone (919)541-7903 | Personal Privacy / Ex. 6

Message

From: Weinstock, Lewis [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DF30E068EFB24A24B35D63BE0596AD9B-LWEINS02]
Sent: 3/7/2019 12:34:43 PM
To: RDemott@ramboll.com
CC: Heidi Hayes [HeidiHayes@eurofinsUS.com]
Subject: FW: Webinar for EPA EtO data for Willowbrook for January 22 - February 11, 2019

FYI

Lewis Weinstock | Office of Air Quality Planning & Standards | U.S. Environmental Protection Agency | Research Triangle Park, NC 27711 | Phone: 919-541-3661|

Subject: Webinar for EPA EtO data for Willowbrook for January 22 - February 11, 2019

EPA webinar: Update of EPA's Ethylene Oxide Monitoring data for Willowbrook, Illinois

The U.S. Environmental Protection Agency will hold a webinar at 3 p.m. central time, Thursday, March 7, 2019 to review air quality monitoring data for Willowbrook, Illinois, covering January 22, 2019 to February 11, 2019. For more information on this webinar, please review the details below:

Webinar:
Date: Thursday, March 7, 2019
Time: 3:00 to 4:00 p.m. (CT)
Meeting Link: https://epawebconferencing.acms.com/willowbrook

Phone line is Personal Privacy / Ex. 6
Access code i

*Note: If you are at a computer, please listen through your computer speakers. We have a capacity of 500 people via computer. If you're not able to be at a computer, you'll be able to listen to the Webinar by phone. The phone line has a capacity of 125.

Materials will be posted on the website after the webinar at https://www.epa.gov/il/sterigenics-willowbrook-facility

If you have never attended an Adobe Connect meeting before, test your connection by visiting http://admin.adobeconnect.com/common/help/en/support/meeting_test.htm. *You may also get a quick overview by visiting* http://www.adobe.com/products/adobeconnect.html.

1. Click "Enter as a Guest"
2. Type in your first & last name and organization
3. Click "Enter Room"
4. You will be in the room!

Appointment

From: Weinstock, Lewis [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df30e068efb24a24b35d63be0596ad9b-LWEINS02]
Sent: 2/25/2019 4:45:05 PM
To: Noah, Greg [Noah.Greg@epa.gov]; Chen, Xi [Chen.Xi@epa.gov]; Dyron.Hamlin@ghd.com; Benjamin.Chandler@ghd.com; Tim Halik [thalik@willowbrook.il.us]; RDemott@ramboll.com; Heidi Hayes [HeidiHayes@eurofinsUS.com]
BCC: RTP-C400C-Max20/RTP-Bldg-C [RTP-C400C-Max20@epa.gov]

Subject: Ethylene Oxide Laboratory/Methods Call Ex. 6 Personal Privacy (PP) code: Ex. 6 Personal Privacy (PP)
Location: RTP-C400C-Max20/RTP-Bldg-C

Start: 2/27/2019 7:00:00 PM
End: 2/27/2019 8:00:00 PM
Show Time As: Tentative

Welcome to our first coordinating call among the groups measuring EtO in the ambient air around Willowbrook. The goal of this call (and others if needed) is to compare notes on the methods being used to report EtO along with any analytical challenges. We can also discuss any questions arising from our joint review of early February collocated sampling results and supporting data packages, assuming that there is sufficient time for a review prior to call. If not, a follow-up call will be scheduled.

Hope this time works for everyone.

Appointment

From: Weinstock, Lewis [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df30e068efb24a24b35d63be0596ad9b-LWEINS02]
Sent: 2/25/2019 4:42:25 PM
To: Noah, Greg [Noah.Greg@epa.gov]; Chen, Xi [Chen.Xi@epa.gov]; Dyron.Hamlin@ghd.com; Benjamin.Chandler@ghd.com; Tim Halik [thalik@willowbrook.il.us]; RDemott@ramboll.com; Heidi Hayes [HeidiHayes@eurofinsUS.com]
BCC: RTP-C400C-Max20/RTP-Bldg-C [RTP-C400C-Max20@epa.gov]

Subject: Ethylene Oxide Laboratory/Methods Call Ex. 6 Personal Privacy (PP) code: Ex. 6 Personal Privacy (PP)
Location: RTP-C400C-Max20/RTP-Bldg-C

Start: 2/27/2019 7:30:00 PM
End: 2/27/2019 8:30:00 PM
Show Time As: Tentative

Welcome to our first coordinating call among the groups measuring EtO in the ambient air around Willowbrook. The goal of this call (and others if needed) is to compare notes on the methods being used to report EtO along with any analytical challenges. We can also discuss any questions arising from our joint review of early February collocated sampling results and supporting data packages, assuming that there is sufficient time for a review prior to call. If not, a follow-up call will be scheduled.

Hope this time works for everyone.

Message

From: Wilson, Holly [Wilson.Holly@epa.gov]
Sent: 5/15/2019 11:17:56 PM
To: laura@kamedulski.com; [redacted]; Jmerrinette@IllinoisRealtors.org; [redacted]; mark.thoman@DGTownship.com; [redacted]; john.j.kim@illinois.gov; Morgan, James [Morgan.James@epa.gov]; drottenberg@atg.state.il.us; thinshaw@indianheadpark-il.gov; ssylvester@atg.state.il.us; [redacted]; echeuse@earthjustice.org; [redacted]; gargano@villageofhinsdale.org; sbucha3@uic.edu; Kim.biggs@illinois.gov; smcivor@darienil.gov; jdurcher@indianheadpark-IL.gov; [redacted]; ehabercoss@tristatefed.com; [redacted]; blaw@hinsdale86.org; vsimon@gower62.com; Ewalter@burr-ridge.gov; kweaver@darienil.gov; kayala@dupagehealth.org; Christopher@dupagehealth.org; Kristen.Jundeen@dupagehealth.org; slibicki@ramboll.com; ssylvester@atg.state.il.us; [redacted]; echeuse@earthjustice.org; [redacted]; Kgargano@villageofhinsdale.org; sbucha3@uic.edu; Kim.biggs@illinois.gov; smcivor@darienil.gov; jdurcher@indianheadpark-IL.gov; [redacted]; ehabercoss@tristatefed.com; [redacted]; blaw@hinsdale86.org; vsimon@gower62.com; Ewalter@burr-ridge.gov; kweaver@darienil.gov; Bcana@darienil.gov; Ivaughan@darienil.gov; [redacted]; tom.cuculich@dupageco.org; Chairman@dupageco.org; Laura.Roche@Illinois.gov; Brad.Frost@illinois.gov; Julie.Armitage@Illinois.gov; Kathy_Weaver@AJG.com; MDUNN@atg.state.il.us; mickey@samusa.com; quino@quino.com; echeuse@earthjustic.org; Curtis.Michols@abbott.com; Bcana@darienil.gov; Ivaughan@darienil.gov; [redacted]; tom.cuculich@dupageco.org; Chairman@dupageco.org; Laura.Roche@Illinois.gov; Brad.Frost@illinois.gov; Julie.Armitage@Illinois.gov; Kathy_Weaver@AJG.com; laura@kamedulski.com; [redacted]; eckters@sbcglobal.net; aeriesfaeries@gmail.com; fayx56@yahoo.com; rodgerhartman@yahoo.com; [redacted]; [redacted]merrinette@IllinoisRealtors.org; [redacted]; [redacted]; mark.thoman@DGTownship.com; [redacted]; john.j.kim@illinois.gov; Morgan, James [Morgan.James@epa.gov]; drottenberg@atg.state.il.us; burdette.diana@gmail.com; jpomio@msn.com; n-loeb@northwestern.edu; LindaQiu2019@nlaw.northwestern.edu; tboci3@gmail.com; Margaret Donnell [Margaret.Donnell@HISCOX.com]
CC: Mckelvey, Laura [Mckelvey.Laura@epa.gov]
Subject: FW: Two webinars posted

FYI… the 4/24 and 4/26 webinars have been closed captioned and posted.

April 26, 2019

The U.S. Environmental Protection Agency held a webinar on Wednesday, April 26, 2019 to review the final set of ethylene oxide air monitoring data in the Willowbrook, IL are.
Slides from the April 26th webinar are available here.
Watch a recording of the webinar here.

April 24, 2019

The U.S. Environmental Protection Agency held a webinar on Wednesday, April 24, 2019 to review Techniques and Skills for Providing Effective Input in the EPA Rulemaking Process.
Slides from the April 24th webinar are available here.
Watch a recording of the webinar here.

Cheers,

Holly

++++++++++++++++++++++++++
Holly Wilson, Lead
Community Air Program
Outreach and Information Division
Office of Air Quality Planning| and Standards
Environmental Protection Agency
MD: C304-03, RM: C-305K
Research Triangle Park, NC 27711
(919)541-5624
wilson.holly@epa.gov

Message

From: Wilson, Holly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=208C5FEA61F24FEFBFD9BB7299F830C1-HWILSON]
Sent: 11/29/2018 1:33:37 AM
To: Kristi Celico Personal Email / Ex. 6 Mckelvey, Laura [Mckelvey.Laura@epa.gov]; doug@forumfg.com; Debra Duerr Personal Email / Ex. 6 Srikant Rao Personal Email / Ex. 6 n Wawak [Personal Email / Ex. 6 Alec.Messina@illinois.gov; Koerber, Mike [Koerber.Mike@epa.gov]; smolinaro@tristatefd.com; pbrenn@tristatefd.com; lawrencelink@tristatefd.com
Subject: EPA Forum: Information For Session Two
Attachments: Willowbrook Open House Resource Tables Final.docx; Willowbrook Community Forum Agenda Final 11.28.18 .docx

Dear Panel members and questioners for Session Two,

Please the attached final agenda and Open House participants. I would like to thank Mayor Tim Hinshaw for agreeing to be a questioner on such short notice☺

If possible, please join us at **1pm at Ashton Place (341 75th St, Willowbrook, IL.)**. We will use that time to go over last minute logistics and instructions from our facilitators. That's also a great time to get acquainted and sort out any clarifying questions.

Thank you for your participation! Please feel free to contact me at Personal Privacy / Ex. 6 if you have any questions.

Cheers,

Holly

++++++++++++++++++++++++++
Holly Wilson, Lead
Community Air Program
Outreach and Information Division
Office of Air Quality Planning and Standards
Environmental Protection Agency
MD: C304-03, RM: C-305K
Research Triangle Park, NC 27711
(919)541-5624
wilson.holly@epa.gov

From: Kristi Celico <kcelico@gmail.com>
Sent: Wednesday, November 28, 2018 5:27 PM
To: Mckelvey, Laura <Mckelvey.Laura@epa.gov>; Wilson, Holly <Wilson.Holly@epa.gov>; doug@forumfg.com; Debra Duerr < Personal Email / Ex. 6 Srikant Rao Personal Email / Ex. 6 John Wawak < Personal Email / Ex. 6 Alec.Messina@illinois.gov; Koerber, Mike <Koerber.Mike@epa.gov>; smolinaro@tristatefd.com; pbrenn@tristatefd.com; lawrencelink@tristatefd.com
Subject: EPA Forum: Information For Session Two

Dear Panel members and questioners for Session Two:

Thanks for agreeing to participate in session two. Below is a summary of your agenda section:

8:30 PM Panel Session 2. Community questions related to the Sterigenics Willowbrook facility
Community Questioners: Sri Rao, Stop Sterigenics Group & John Wawak, Stop Sterigenics Group

Panelists:

- Tri-State Fire Department –Sammy Molinaro, Chief & Patrick Brenn, Deputy Chief
- US EPA – Mike Koerber, Deputy Office Director, Office of Air Quality Planning and Standards (OAQPS)
- Illinois EPA – Alec Messina, Director

EPA will be sending an updated agenda soon.

It is our understanding that Chief Molinaro has a 10-minute presentation he would like to make. Generally speaking, we have eliminated presentations, but we agree that it is important for him to share this information and will make time for it.

Attached please find two documents:

- The list of raw questions that came in from the public. Two things: Some community members submitted over 60 pages of questions. EPA summarized these. Also, some additional questions came in after the Monday night deadline. Congressman Lipinski encouraged folks to send in questions in a recent mailing, but did not note the cut-off date. We will try to deal with these as best as possible by including them in the Q and A session. Please note this document is an Excel sheet and it has two pages to it.
- An organized and streamlined version of the questions to help focus the panel interaction. Please note this is an Excel Sheet. Go to Session two of this document. EPA reviewed all the questions and tried to identify ones that:
  - Are of greatest concern to the community (e.g., many people asked it);
  - Are best for a public forum (e.g., not questions about the details of a particular individual's health problem—but instead those that address community health concerns).
  - Help share most of the key information in an order that makes some logical sense.

Sri and John will be asking the questions. The questioners can ask follow-up questions if they do not understand the answer or feel that the response does not answer the question. The challenge will be there is only 1/2 hour for this session--so it is your job to thoughtfully get through as many questions as possible within the limited time. (Please know that EPA has agreed to answer most all the questions they received in writing too. These will be posted on their website at a later time.)

A couple of tasks:

- If your name or title above is wrong, please contact Holly immediately. Her email is Wilson.holly@epa.gov
- Please review the questions in the second attachment for completeness and flow. If you have suggestions for change, please send them back to everyone on this email so that we can try to get quick resolution. If necessary, we will schedule a conference call. Given the tightness of the schedule, please include your recommended change--do not just state a concern. Please send any suggestions by no later than noon on Thursday.

We fully appreciate this is a challenging task and a tight schedule. We are very grateful for all of you for working under these difficult conditions.

Doug Sarno and Kristi Celico

Meeting Facilitators --

Kristi Parker Celico
Public Policy Mediator/Facilitator

Personal Privacy / Ex. 6

Message

From: Wilson, Holly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=208C5FEA61F24FEFBFD9BB7299F830C1-HWILSON]
Sent: 5/15/2019 1:02:14 AM
To: rick.cobb@illinois.gov
Subject: FW: IEPA Well Study
Attachments: 5.29 Willowbrook Meeting Draft Agenda as of 5 9 19 HW.docx

Hi Rick,

Hope this email finds you well. I'm sure you have heard about the EtO Public Meeting in Burr Ridge, May 29th at the Burr Ridge Marriott (meeting announcement below). I know that the results of the IEPA Well Study have been posted, however there is still quite a bit of interest from the community in hearing about the study from agency staff. To that end, community members on the meeting planning team have requested that a formal presentation be made during the Community Meeting:6pm-10pm. I was told that you were the subject matter expert on the study and I would like to invite you to share your report synopsis. I have attached the meeting agenda for your information. Pls let me know if you are the right person for this request.

I am happy to chat if you have additional questions.

Cheers,

Holly

++++++++++++++++++++++++
Holly Wilson, Lead
Community Air Program
Outreach and Information Division
Office of Air Quality Planning and Standards
Environmental Protection Agency
MD: C304-03, RM: C-305K
Research Triangle Park, NC 27711
(919)541-5624
wilson.holly@epa.gov

Meeting Announcement
The U.S. EPA will host an open house and community meeting to provide updates on the agency's work to better understand air emissions of ethylene oxide from the Sterigenics facility in Willowbrook, Illinois. Both will be held Wednesday, May 29, 2019 at the Marriott Chicago Southwest at Burr Ridge, 1200 Burr Ridge Parkway, Burr Ridge, Illinois, 60527

Open House: 2 to 5 p.m. Central time.
The open house will provide an opportunity for individuals to talk one-on-one with staff from U.S. EPA and other agencies about their concerns related to ethylene oxide and to ask questions.

Community Meeting: 6 to 10:00 p.m. Central time.
The community forum will feature a series of presentations from federal and state agencies that have been examining issues related to ethylene oxide from the Sterigenics facility. Staff from U.S. EPA, the Agency for Toxic Substances and Disease Registry, the Illinois Department of Public Health and the Illinois Environmental Protection Agency will provide updates on their work. A citizen panel will ask questions related to the agencies' reports that are most important to the community.

Message

From: Wilson, Holly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=208C5FEA61F24FEFBFD9BB7299F830C1-HWILSON]
Sent: 5/15/2019 5:08:57 PM
To: sbucha3@uic.edu; kim.biggs@illinois.gov; jdurocher@indianheadpark-IL.gov; Srikant Rao Personal Email / Ex. 6 Urszula Tanouye Personal Email / Ex. 6 ; Victor Simon [vsimon@gower62.com]; Evan Walter [EWalter@burr-ridge.gov]; Dr. Tiefu Shen: [tiefu.shen@illinois.gov]; Kyle.Garner@Illinois.gov; Douglas Pollock [DPOLLOCK@BURR-RIDGE.GOV]; Roche, Laura [Laura.Roche@Illinois.Gov]; Frost, Brad [Brad.Frost@Illinois.gov]; Cuculich, Thomas [Thomas.Cuculich@dupageco.org]; Dunn, Matthew [MDunn@atg.state.il.us]; Kristi Celico Personal Email / Ex. 6 mna9@cdc.gov; Nam, Ed [nam.ed@epa.gov]; Prentiss,Tamara [tprentis@hinsdale86.org]; Karen J. Ayala [kayala@dupagehealth.org]; Ward, Hillary [Ward.Hillary@epa.gov]; Beckmann, Ronna Erin [beckmann.ronna@epa.gov]; Gayle Neal [gneal@willowbrook.il.us]; mkj5@cdc.gov; Village Administrator [villageadmin@willowbrook.il.us]; Kottmeyer, Nick [Nick.Kottmeyer@dupageco.org]; Bendinelli, Angela [ABendinelli@dupageco.org]; Sieffert, Margaret [Sieffert.Margaret@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]; Margaret Donnell [Margaret.Donnell@HISCOX.com]; Furey, Eileen [furey.eileen@epa.gov]; Kelley, Jeff [kelley.jeff@epa.gov]; Singer, Joshua [Singer.Joshua@epa.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]; Mckelvey, Laura [mckelvey.laura@epa.gov]; Hart, Greg [Greg.Hart@dupageco.org]; Hinz, Joy [Joy.Hinz@dupageco.org]; Renehan, Julie [Julie.Renehan@dupageco.org]; Walts, Alan [walts.alan@epa.gov]; doug (doug@forumfg.com) [doug@forumfg.com]; Doug Sarno [sarno@theparticipationcompany.com]; Cutrona, Jennifer L Personal Email / Ex. 6
CC: Holly Wilson (Wilson.Holly@epa.gov) [Wilson.Holly@epa.gov]
Subject: EPA Webinar: Air Toxics Risk Assessment 101
Attachments: Public meeting notice for 5.29.19 _1.pdf

Hello All,
Trying to reduce the number emails☺ Please see the details below for our upcoming webinar on risk assessment and the attached meeting announcement.

EPA Webinar: Air Toxics Risk Assessment 101

The U.S. Environmental Protection Agency (EPA) will hold an Air Toxics Risk Assessment 101 webinar at 4 p.m. Central daylight time, Monday, May 20, 2019, to provide information about how the Agency assesses risk from air toxic pollutants in the outdoor air. EPA is holding the webinar to provide residents of the Willowbrook, Illinois area basic information on risk assessments in advance of the release of the Agency's assessment of risk from the Sterigenics Willowbrook facility later this month. EPA will present results of the Sterigenics risk assessment at a public meeting May 29, 2019.

Instructions for attending the webinar are below:

Webinar:
Date: Monday, May 20, 2019
Time: 4:00 to 5:00 (CDT)
Meeting Link: https://epawebconferencing.acms.com/willowbrook

Phone line is
Access code Personal Privacy / Ex. 6

*Note: If you are participating via a computer, please listen through your computer speakers. We have a capacity of 500 people via computer. If you're not able to be at a computer, you'll be able to listen to the Webinar by phone. The phone line has a capacity of 125.

Materials will be posted after the webinar at https://www.epa.gov/il/sterigenics-willowbrook-facility

If you have never attended an Adobe Connect meeting before, test your connection by visiting http://admin.adobeconnect.com/common/help/en/support/meeting_test.htm. *You may also get a quick overview by visiting* http://www.adobe.com/products/adobeconnect.html.

1. Click "Enter as a Guest"
2. Type in your first & last name and organization
3. Click "Enter Room"
4. You will be in the webinar!

Holly

++++++++++++++++++++++++++
Holly Wilson
Outreach and Information Division
Office of Air Quality Planning| and Standards
Environmental Protection Agency
MD: C304-03, RM: C-305K
Research Triangle Park, NC 27711
(919)541-5624
wilson.holly@epa.gov